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| Clinical Trial Information | | | |
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| **Trial Title** | Study of Lifileucel (LN-144), Autologous Tumor Infiltrating Lymphocytes, in the Treatment of Patients with Metastatic Melanoma (LN-144) | | |
| **Drug(s)/Molecule(s)** | lifileucel; | **Trial Identifier** | GDCT0232927 |
| **Secondary ID(s)** | NCT02360579; C-144-01;GDC40003238;GDCT0231030;NCI-2015-01957;CDR769149;2017-000760-15;EudraCT-2017-000760-15;18309;P 54117;S16-00804;UKCTG-39529;2017-02031;BASEC2017-02031;EUCTR2017-000760-15;SNCTP000002819;2017-000760-15-GB | | |
| **Sponsor (s)** | Iovance Biotherapeutics Inc | **Indication** | Melanoma, Metastatic Melanoma |
| **Trial Status** | Completed | **Trial Phase** | Phase II |
| **Approved Health Authority** | France: National Agency of Medicine and Health Product Safety (ANSM); Hungary: National Institute of Pharmacy (NIP); Spain: Spanish Agency of Medicines and Medical Devices (AEMPS); United Kingdom: Medicines and Healthcare products Regulatory Agency (MHRA) | | |
| **Secondary Intervention** | aldesleukin, Cytoxan, fludarabine phosphate | | |

| Clinical Trial Details | |
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| Trial Title | Study of Lifileucel (LN-144), Autologous Tumor Infiltrating Lymphocytes, in the Treatment of Patients with Metastatic Melanoma (LN-144) |
| Official Title | A Phase II, Multicenter Study to Assess the Efficacy and Safety of Autologous Tumor Infiltrating Lymphocytes (LN-144) for Treatment of Patients with Metastatic Melanoma |
| Acronym | InnovaTIL-01 |
| Study Type | Interventional |
| Therapy Type | Monotherapy; Combination Therapy |
| Actual Start Date | 14 Sep 2015 |
| Actual End Date | 26 May 2022 |
| Trial Duration (in Months) | 81.53 |
| Study Designs | |
| Decentralized/Virtual Trials | Yes |

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| Decentralized/Virtual Component | Telemedicine |
| Purpose | The purpose of this study was to evaluate safety, pharmacodynamics and efficacy of autologous TILvia infusion of LN-144 (autologous TIL) followed by interleukin 2 (IL 2) after a nonmyeloablative lymphodepletion (NMA-LD) preconditioning regimen. |
| Primary Outcome Measure(s)/Objective(s) | • Disease Assessment for Objective Response Rate - Every 6 weeks for 6 months, then every 3 months for a maximum of 60 months<br>  ○ Evaluate the efficacy of LN-144 in patients with unresectable or metastatic melanoma using the objective response rate (ORR), as assessed by the Blinded Independent Review Committee (BIRC) per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1<br>• To evaluate lifileucel (LN-144) reduces or slows the progression of metastatic melanoma<br>• To evaluate lifileucel (LN-144) eliminates all detectable metastatic melanoma<br>• To evaluate treatment with lifileucel (LN-144) extends the life of a subject without their cancer worsening |
| Secondary Outcome Measure(s)/Objective(s) | • Disease Assessment for Duration of Response - Every 6 weeks for 6 months, then every 3 months for a maximum of 60 months<br>  ○ Evaluate the efficacy endpoints of duration of response (DOR) by the BIRC and by the investigator per RECIST v11<br>• Disease Assessment for Disease Control Rate - Every 6 weeks for 6 months, then every 3 months for a maximum of 60 months<br>  ○ Evaluate the efficacy endpoints of disease control rate (DCR) as assessed by the BIRC and by the investigator per RECIST v11<br>• Disease Assessment for Progression-Free Survival - Every 6 weeks for 6 months, then every 3 months for a maximum of 60 months<br>  ○ Evaluate the efficacy endpoints of progression-free survival (PFS) as assessed by the BIRC and by the investigator per RECIST v11<br>• Overall Survival - Until death or up to 60 months<br>  ○ Evaluate overall survival (OS) and objective response rate (ORR) by the investigator<br>• Adverse Events - Maximum 60 months<br>  ○ Incidence rate of treatment-emergent adverse events (AEs) and serious AEs by severity and relationship to Lifileucel (LN-144)<br>• To assess safety and efficacy |

<table>
<tr><td></td><td>
<ul>
<li>Response to lifileucel was assessed by IRC (RECIST v1.1)</li>
<li>Tumors resected for lifileucel manufacturing (after ICI exposure) were analyzed for TCR clonality, tumor mutational burden (TMB), gene expression, and gene mutations</li>
<li>Hierarchical clustering of immune-related signatures was performed</li>
<li>DOR, PFS, OS, TEAE incidence and severity</li>
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</td></tr>
<tr><td>Trial Description</td><td>This was an interventional, phase II, uncontrolled, non-randomized, cohort, pivotal, global, parallel assignment, exploratory, multi-cohort, three-cohort, open-label, prospective, pharmacogenetics, treatment and multi-centered study to assess the safety, feasibility, pharmacodynamics and efficacy of cell transfer therapy using autologous tumor infiltrating lymphocytes (LN-144) followed by IL-2 in the treatment of subjects with refractory metastatic melanoma. Subjects were divided into four cohorts:
<table>
<tr><th>Cohorts</th><th>Type</th><th>Assigned Intervention</th><th>Description</th></tr>
<tr><td>I (n=30)</td><td>Experimental</td><td>LN-144 (Closed to enrollment)</td><td>Subjects received Lifileucel (LN-144) which was a tumor sample was resected from each subject and cultured ex vivo to expand the population of tumor infiltrating lymphocytes. After lymphodepletion, subjects were infused with Lifileucel followed by IL-2 without cryopreservation(Gen 1 infusion product) (Closed)</td></tr>
<tr><td>II (n=66)</td><td>Experimental</td><td>LN-144 (Closed to enrollment)</td><td>Subjects received Lifileucel (LN-144) which was a tumor sample was resected from each subject and cultured ex vivo to expand the population of tumor infiltrating lymphocytes. After one week of lymphodepletion, subjects were infused with Lifileucel followed by ≥6 IL-2 with cryopreservation (Gen 2 infusion product)</td></tr>
<tr><td>III (n=10)</td><td>Experimental</td><td>LN-144 (re-treatment)</td><td>Subjects from cohort 1 or Cohort 2 may rescreen for a second TIL regimen therapy if they meet all inclusion and exclusion Criteria (except exclusion criterion b) followed by IL-2 (600,000 IU/kg) up to 6 doses</td></tr>
<tr><td>IV</td><td>Experimental</td><td>LN-144 with</td><td>Subjects after lymphodepletion,</td></tr>
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| | <table><tr><td>(n=75)</td><td></td><td>cryopreservation (Gen 2 infusion product) (Closed to enrollment)</td><td>subjects were infused with Lifileucel followed by IL-2</td></tr></table><br>A tumor sample was resected from each subject and cultured ex vivo to expand the population of tumor infiltrating lymphocytes. After lymphodepletion, subjects were infused with the autologous TIL (LN-144) followed by IL-2. Lymphodepletion chemotherapy (fludarabine phosphate (25 mg/m$^2$/d × 5d) concentrate for solution for injection/infusion at a dose of 25 mg/ml intravenously and cyclophosphamide powder (60 mg/kg/d × 2d) for solution for injection at a dose of 1 g intravenously) for one week followed by a single high dose Ia single lifileucel infusion, and up to 6 IL-2 doses starting the morning on the next day after infusion. Subjects were evaluated for response approximately 12 weeks following the LN-144 therapy. Subjects received one course of treatment.<br>• Cohort 1: Non-cryopreserved TIL product (Gen 1) (N=30)<br>• Cohort 2: Cryopreserved lifileucel (Gen 2) (N=66)<br>• Cohort 3: TIL re-treatment (N=~10)<br>• Cohort 4: Single arm Pivotal Cryopreserved lifileucel (Gen 2) (N=75)<br><br>The first two cohorts were evaluating two different manufacturing processes for LN-144. Subjects in cohort one were receiving fresh, non-cryopreserved TIL, cohort two subjects were receiving product manufactured through a more streamlined and rapid three-week procedure yielding a cryopreserved product and retreatment with LN144 for the subjects without response or who progress after initial response. Retreatment with LN-144 for subjects without response or who progress after initial response was done. This was a one-time therapy, and there was no post-study treatment. There a three year follow-up for overall survival (OS) after last subject in. The treatment regimen included preparative lymphodepletion (cyclophosphamide 60 mg/kg/d × 2d, fludarabine 25 mg/m$^2$/d × 5d), a single lifileucel infusion, and up to 6 doses of high-dose IL-2 (600,000 IU/kg). Subjects completing treatment were assessed for effectiveness and safety of LN-144 treatment at weeks 2, 4, 6 following LN-144 treatment, and then once every 6 weeks for up to 6 months. after treatment. After 6 months, subjects were assessed again at 9, 12, 18 and 24 months after treatment, then every 3 months for up to 5 years. Monitoring of overall survival began at the end of the response evaluation period and continue by telephone contact every 3 months for a maximum period of 5 years for each subject from the last treatment of the 'study. A total of 181 subjects were enrolled in this study. |
| Trial Notes | As per the second quarter and first half 2023 financial results and corporate updates August 2023, study results expected to be presented at European Society for Medical Oncology (ESMO CONGRESS) 2023, October 20-24, 2023, Madrid, Spain. |

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| | https://ir.iovance.com/node/13881/pdf (Page No: 02) As per the third quarterly report (FORM 10-Q) September 2022, study additional data from Cohorts 2 and 4 at the Society for Immunotherapy of Cancer's Annual Meeting, or SITC, expected to be presented in November 2022. https://www.sec.gov/ix?doc=%2FArchives%2Fedgar%2Fdata%2F1425205%2F0001558370220162 95%2Fiova-20220930x10q.htm (Page No: 29) As of August 2022, study additional results expected at a medical meeting later this year. https://www.globenewswire.com/news-release/2022/08/25/2504495/0/en/Iovance-Biotherapeutics-Initiates-Biologics-License-Application-BLA-Submission-for-Lifileucel-in-Advanced-Melanoma.html As per May 2022, study expected to present additional data from Cohorts 2 and 4 at a medical meeting in the second half of 2022. https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data As per the corporate overview presentation May 2022, study cohort 4 data expected in 2022. https://ir.iovance.com/static-files/1fd55821-d1ee-4403-8aa5-7f25f83894b1 (Slide no: 30) As per the company presentation at the Chardan's 6th Annual Virtual Genetic Medicines and Cell Therapy Manufacturing Summit, study cohort 4 data expected in 2022. https://wsw.com/webcast/chard11/iova/1911420-(Slide No:29) As per the corporate overview presentation March 2022, study cohort 4 data expected in 2022. https://ir.iovance.com/static-files/efb8f5d3-1eb0-4bc0-baf7-8ff5c54e6dbd (Slide no: 28)<br><br>As per the company presentation at the Virtual 40th Annual J.P. Morgan Healthcare Conference, study cohort 4 data expected in 2022. https://ir.iovance.com/static-files/3f991737-1354-441b-9ba2-e4231f1fb3d5 (Slide 27) As per the first quarter 2021 financial results, cohort 2 data accepted for an oral presentation at the upcoming American Society of Clinical Oncology (ASCO) Annual Meeting. cohort 2 data has also been accepted for a forthcoming publication in a high impact oncology journal. https://www.globenewswire.com/news-release/2021/05/06/2224972/0/en/Iovance-Biotherapeutics-Reports-First-Quarter-2021-Financial-Results-and-Corporate-Updates.html As of April 2021, study data expected to be presented at the upcoming ASCO 2021 Annual Meeting, to be held June 4-8, 2021. https://www.globenewswire.com/news-release/2021/04/28/2218849/0/en/Iovance-Biotherapeutics-to-Present-Clinical-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html Based on the primary research from insights, study data expected by year end. As of May 2020, additional updates on Cohort 4 expected to present at upcoming medical meetings. https://www.globenewswire.com/news-release/2020/05/27/2039716/0/en/Iovance-Reports-Pivotal-Cohort-4-Data-for-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Lifileucel-from-C-144-01-Clinical- |

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| | Study-in-Advanced-Melanoma.html As of April 2020, new interim data from Cohort 2 expected to present at American Society of Clinical Oncology's (ASCO) 2020 Virtual Program. https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-present-updated-data-clinical-study As of Fourth Quarter and Full-Year 2019 Financial Results, cohort 4 of the C-144-01 study was initiated in March 2019 and completed in January 2020. https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-1 As per the corporate presentation February 2020, study top line data expected in 2020. https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f (Slide no: 50) Based on the Primary Research from Insights, cohort 4 enrollment completion expected in first quarter of 2020. As per the company presentation November 2019, study enrollment completion expected in 2020. http://ir.iovance.com/static-files/b61c8cbf-390b-42fc-accf-aa67941cd068 (Slide no: 06) As per the corporate presentation November 2019, study enrollment completion expected in 2020. http://ir.iovance.com/static-files/1b1e5731-fa4e-4341-8454-eec6e83ff2ce (Slide No: 05) As per third quarter financial results, Independent Review Committee (IRC)-read results from Cohort 2 expected to present at the upcoming Society for Immunotherapy of Cancer (SITC) meeting. http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-third-quarter-and-september-year As per the corporate Presentation October 2019, study expects enrollment completion for cohort 4 in 2020. http://ir.iovance.com/static-files/f31d23c0-b015-4ac4-a2bc-5b41dbadfdf5 (Slide No: 05) As per the Houston Oncology Summit Presentation October 2019, cohort 2 IRC data expected in fourth quarter of 2019. http://ir.iovance.com/static-files/47dfc7e0-e16f-4332-b24e-72e53e59c702 (Slide No: 06) As per the Investor Presentation July 2019, the study expects enrollment completion for cohort 4 in 2020. http://ir.iovance.com/static-files/885a2bb7-8102-4b2c-95d1-e905679b2845 (Slide no: 3) As per the corporate presentation July 2019, cohort 4 expected to complete enrollment in 2020. http://ir.iovance.com/static-files/633da1e2-5d44-4513-8223-75317481f580 (Slide No. 03) As per the corporate presentation May 2019, full cohort 2 expected to be presented at the American Society of Clinical Oncology ASCO June 2019. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA2ODY4fENoaWxkSUQ9NDE5NjA4fFR5cGU9MQ==&t=1 (Slide No: 15) As per the corporate presentation April 2019, updated data from the cohort 2 expected to be presented at the American Society of Clinical Oncology ASCO June 2019. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA1NDUzfENoaWxkSUQ9NDE3ODczfFR5cGU9MQ==&t=1 (Slide No: 14) As per the corporate presentation March 2019, completion of enrollment in cohort 4 expected in 2020. phx.corporate- |

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| | ir.net/External.File?item=UGFyZW50SUQ9NzA1MTUwfENoaWxkSUQ9NDE3NDkyfFR5cGU9MQ==&t=1 (Slide No: 03, 04, 11, 14-21) As per the annual report (FORM 10-K) 2018, subjects enrollment in cohort 4 expected in early 2019.<br>services.corporate-ir.net/SEC/Document.Service?id=P3VybD1hSFIwY0RvdkwyRndhUzUwWlc1cmQybDZZWEprTG1OdmJTOWtiM2R1Ykc5aFpDNXdhSEEvWVdOMGFXOXVQVkJFUmlacGNHRm5aVDB4TWpjME1UYzJOU1p6ZFdKemFXUTlOVGM9JnR5cGU9MiZmbj1Jb3ZhbmNlQmlvdGhlcmFwZXV0aWNzSW5jLnBkZg== (Page No: 66) As per the corporate presentaion February 2019, subjects enrollment in cohort 4 expected in 2019. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAzOTUzfENoaWxkSUQ9NDE2MTI1fFR5cGU9MQ==&t=1 (Slide No. 34)<br><br>As per the company presentation at the 37th Annual JP Morgan Healthcare Conference, enrollment in registrational cohort expected in 2019. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1 (Slide 04, As per the corporate presentation January 2019, subjects enrollment in cohort 4 expected in early 2019. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1 (Slide No: 19) As per the corporate presentation November 2018, subjects enrollment in cohort 4 expected in early 2019. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyNjIyfENoaWxkSUQ9NDE0NTY5fFR5cGU9MQ==&t=1 (Slide No: 13) As per the company clinical program update presentation November 2018, subjects enrollment in cohort 4 expected in early 2019. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAxNzc0fENoaWxkSUQ9NDEzNTM2fFR5cGU9MQ==&t=1 (Slide No: 09) As of October 2018, enrollment initiation in fourth cohort expected in early 2019 and full enrollment expected by late 2019/early 2020. In new cohort expect to enroll 80-100 subjects with a prospective definition of primary endpoint of objective response rate to be read out by a Blinded Independent Review Committee (BIRC) to support registration of lifileucel. http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2371343 As per the corporate presentation October 2018, enrollment of subjects ongoing.<br>phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAwMjU4fENoaWxkSUQ9NDExODcyfFR5cGU9MQ==&t=1 (Slide No: 10, 13) As per the corporate presentation September 2018, enrollment of subjects ongoing. phx.corporate- |

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| | ir.net/External.File?item=UGFyZW50SUQ9Njk5NjIyfENoaWxkSUQ9NDExMTMwfFR5cGU9MQ==&t=1 (Slide No: 13) As per the corporate presentation August 2018, enrollment of subjects ongoing. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk4OTQyfENoaWxkSUQ9NDEwMzk2fFR5cGU9MQ==&t=1 (Slide No.17) As per the second quarter (FORM 10-Q) 2018, enrollment of subjects ongoing. services.corporate-ir.net/SEC/Document.Service?id=P3VybD1hSFIwY0RvdkwyRndhUzUwWlc1cmQybDZZWEprTG1OdmJTOWtiM2R1Ykc5aFpDNXdhSEEvWVdOMGFXOXVQVkJFUmlacGNHRm5aVDB4TWpNNU16QTJNQ1p6ZFdKemFXUTlOVGM9JnR5cGU9MiZmbj1Jb3ZhbmNlQmlvdGhlcmFwZXV0aWNzSW5jLnBkZg==&t=1 (Page No: 21) Based on the Primary Research from Insights, updated data from the study to be presented at an upcoming medical meeting in the second half. As per the corporate presentation June 2018, enrollment of subjects ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk1Nzk4fENoaWxkSUQ9NDA3MTI1fFR5cGU9MQ==&t=1 (Slide No: 05) As per the company corporate presentation June 2018, enrollment of subjects ongoing. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk1NTA2fENoaWxkSUQ9NDA2NzgxfFR5cGU9MQ==&t=1 (Slide No: 05)<br><br>As of June 2018, enrollment ongoing in the United States and Europe and 25 clinical sites activated in the United States and Europe. http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2353696 As per the first quarter 2018 financial results, 60 subjects from cohort 2 expected to utilize Gen 2 manufacturing process. http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2348539 As per the company corporate presentation May 2018, enrollment of subjects ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkzNDU3fENoaWxkSUQ9NDA1NjIzfFR5cGU9MQ==&t=1 (Slide No: 05) As per the company corporate presentation May 2018, enrollment of subjects ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkzNDU3fENoaWxkSUQ9NDA0Njc2fFR5cGU9MQ==&t=1 (Slide No: 05)<br><br>As per the company update presentation April 2018, enrollment of subjects ongoing. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkyMTU3fENoaWxkSUQ9NDAzMTM5fFR5cGU9MQ==&t=1 (Slide No: 05) As per the company corporate presentation April 2018, enrollment of subjects ongoing. |

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| | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkxODk3fENoaWxkSUQ9NDAyODQ5fFR5cGU9MQ==&t=1 (Slide No: 05) As per the company corporate presentation April 2018, enrollment of subjects ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkxMjMyfENoaWxkSUQ9NDAyMDk1fFR5cGU9MQ==&t=1 (Slide No: 04, 05) As per the company corporate presentation March 2018, enrollment of subjects ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkwNzU1fENoaWxkSUQ9NDAxNDI1fFR5cGU9MQ==&t=1 (Slide No: 04, 05) As per the fourth quarter and final year 2018, first clinical site was activated in Europe. http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2337617 As per the company corporate presentation March 2018, enrollment of subjects was ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkwMTQ5fENoaWxkSUQ9NDAwNTc3fFR5cGU9MQ==&t=1 (Slide No: 04, 05, 17-22) As per the company corporate presentation February 2018, enrollment of subjects was ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg4Njk4fENoaWxkSUQ9Mzk5MDIxfFR5cGU9MQ==&t=1 (Slide No: 04, 05, 17-22)<br><br>As per the company corporate presentation January 2018, enrollment of subjects was ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg3NDAwfENoaWxkSUQ9Mzk3NTc1fFR5cGU9MQ==&t=1 (Slide No: 04, 05, 17-22) As per the company corporate presentation January 2018, enrollment of subjects was ongoing. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg2Mzg0fENoaWxkSUQ9Mzk2NjEyfFR5cGU9MQ==&t=1 (Slide No: 05, 17, 18, 19, 20, 21, 22) As of December 2017, enrollment in Europe expected to begin in first early 2018. http://globenewswire.com/news-release/2017/12/13/1261171/0/en/Iovance-Biotherapeutics-Announces-Manufacturing-Decision-Provides-Clinical-Updates-and-Highlights-Pipeline-Expansion-at-Analyst-Day-2017.html As per the company analyst and investor day presentation December 2017, enrollment of subjects was ongoing. https://edge.media-server.com/m6/p/fhqnhyoj (Slide No: 20, 23) As per the company update presentation at the Jefferies 2017 London Healthcare Conference, study enrolling. http://wsw.com/webcast/jeff108/iova/ (Slide No:5,15) As per the third quarter report (FORM-10Q) 2017, enrollment of the study was ongoing. http://services.corporate-ir.net/SEC/Document.Service?id=P3VybD1hSFIwY0RvdkwyRndhUzUwWlc1cmQybDZZWEprTG1OdmJTOWtiM2R1Ykc5aFpDNXdhSEEvWVdOMGFXOX |

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| | VQVkJFUmlacGNHRm5aVDB4TVRnMk9ESTRPQ1p6ZFdKemFXUTlOVGM9JnR5cGU9MiZmbj1Jb3ZhbmNlQmlvdGhlcmFwZXV0aWNzSW5jLnBkZg==( Page no. 20) As per the third quarter financial results 2017, LN-144 a late-breaking abstract is expected to present at Society for Immunotherapy of Cancer (SITC) Annual Meeting 2017 http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2312953 As per the company investor presentation November 2017, study was enrolling. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjgzMjA1fENoaWxkSUQ9MzkyODA2fFR5cGU9MQ==&t=1 (Slide no:5,25) As per the company investor presentation October 2017, enrollment completion expected in 2017. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjgwMTkxfENoaWxkSUQ9Mzg5NTIxfFR5cGU9MQ==&t=1 (Slide No. 05, 21) As per the company investor presentation September 2017, study currently enrolling. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njc5NjY0fENoaWxkSUQ9Mzg4ODc4fFR5cGU9MQ==&t=1 (Slide No. 05,25) Based on the Primary Research from Insights, 18 subjects enrolled at one site and further information from arm two and three of the study expected later this year. As per the Investor presentation June 2017, study was ongoing. http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njc0NjA3fENoaWxkSUQ9MzgyNzk0fFR5cGU9MQ==&t=1 (Slide no. 05, 17-25) As per the company corporate Presentation, June 2017, study enrolling subjects. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjczMjQzfENoaWxkSUQ9MzgxMDU1fFR5cGU9MQ==&t=1 (Slide 05) As per the abstract presented in the American Society of Clinical Oncology Annual Meeting (ASCO 2017), this study will be expanded to enroll subjects with a shorter manufacturing process as well as offering re-treatment for study subjects. http://abstracts.asco.org/199/AbstView_199_185466.html As of May 2017, interim data from the first cohort expected to be present at 2017 American Society of Clinical Oncology Annual Meeting in June 2017. http://content.equisolve.net/lbio/news/2017-05-19_Lion_Biotechnologies_Announces_First_Patient_97.pdf As per the first quarter (FORM 10-Q) fiscal year 2017 report, the study was being conducted at ten sites and enrolling subjects. http://ir.lbio.com/all-sec-filings/content/0001144204-17-024234/0001144204-17-024234.pdf (Page 18) As per the company presentation April 2017, the enrollment of subjects was ongoing. http://c.eqcdn.com/_bf157f4130ca07e341a5ae6bec207098/lbio/db/230/543/pdf/Lion+Investor+Pres-April+2017-Final.pdf (Slide 05) As per the company presentation at the 37th Cowen and Company Annual Health Care Conference, the enrollment for the study was ongoing. |

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| | http://www.wsw.com/webcast/cowen38/lbio/?lobby=true&day=1 (Slide 06) As per the annual report (FORM 10-K) 2016, enrollment was ongoing and the interim data expected in 2017. http://ir.lbio.com/all-sec-filings/content/0001144204-17-013535/0001144204-17-013535.pdf (Pages 02, 03) As per fourth quarter and full-year 2016 financial results and provides corporate update, interim results from the trial expected to be presented in upcoming medical meeting. http://www.lbio.com/news-media/press-releases/detail/90/lion-biotechnologies-reports-fourth-quarter-and-full-year As per the company corporate presentation February 2017, the enrollment of subjects expected to complete in 2017. http://c.eqcdn.com/_93704e407668de42964c35376b16cc98/lbio/db/230/543/pdf/Lion+Investor+Pres-+Feb+Final.pdf (Slide 31) As per the company corporate presentation January 2017, the enrollment of subjects was ongoing. http://c.eqcdn.com/_e05c3f35ad3f18a8dfe6b487716f1d1d/lbio/db/230/543/pdf/Lion+Investor+Pres-+Jan+2017-+FINAL+1.7+9am.pdf(Slide 07) As per the company corporate presentation November 2016, enrollment of subjects was ongoing.<br>http://c.eqcdn.com/_20bd70a21ba0b232e63b6095307647e2/lbio/db/230/543/pdf/Lion+Investor+Pres-9+Nov+2016-+FINAL.pdf (Slide 07)<br>http://www.lbio.com/pipeline As per the third quarter report (FORM 10-Q) 2016, enrollment of the subjects was ongoing. http://ir.lbio.com/all-sec-filings/content/0001144204-16-131686/v451596_10q.htm?TB_iframe=true&height=auto&width=auto&preload=false (Page 21) As per the company presentation at the Jefferies 2016 Healthcare Conference, the enrollment was ongoing and a total of 25 subjects planned for enrollment.<br>http://wsw.com/webcast/jeff97/lbio/?lobby=true (Slides 08, 09) As per the first quarter report (FORM 10-Q) 2016, the study was initiated in third quarter of 2015.<br>ir.lbio.com/all-sec-filings/content/0001144204-16-099858/0001144204-16-099858.pdf As of January 2015, company was filed an investigational new drug (IND) application with the United States FDA to conduct the study.<br>As of February 2015, the US Food and Drug Administration (FDA) accepted the investigational new drug (IND) application to initiate the study. The study was conducted at up to five sites.<br>As of September 2015, enrollment of subjects was initiated in the study. Initial results from the study expected to be reported in 2016. The study was being conducted at up to five sites.<br>As per the company presentation at the Jefferies 2015 Global Healthcare Conference, the product was in phase II stage of development and the trial expected to initiate by the third quarter of 2015.<br>As per the annual report (FORM 10-K) 2015, enrollment was opened in the second half of that year. The study was being conducted at ten clinical sites.<br>As per the annual report (FORM 10-K) 2014, the company was planned to initiate the study in mid-2015.<br>As of December 2014, the trial initiation expected in the first quarter of 2015. |

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| | http://www.lbio.com/news-media/press-releases/detail/30/lion-biotechnologies-names-elma-hawkins-president-chief |

| Sponsor(s)/Collaborator(s) | |
|---|---|
| **Sponsor(s)/CRO(s) - Type & Details** | |
| Sponsor | Iovance Biotherapeutics Inc |
| CRO | PRA Health Sciences Inc (Subsidiary of ICON Plc) |

**Drug Details**

Primary Interventions(s)

| Generic Name | Route of Administration |
|---|---|
| lifileucel | Intravenous; Intravenous Drip |

Secondary Interventions(s)

| Generic Name | Route of Administration |
|---|---|
| aldesleukin | Intravenous; Subcutaneous |
| Cytoxan | Intramuscular; Intravascular; Intravenous; Oral |
| fludarabine phosphate | Intravenous |

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| Drug Name | lifileucel (Pipeline Drug) |
| Drug Description | Lifileucel (Amtagvi) is a tumor-derived autologous T cell immunotherapy agent. It is formulated as suspension for intravenous infusion. Amtagvi is indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor. Lifileucel (LN-144) is under development for the treatment of endometrial cancer, relapsed/refractory metastatic melanoma, recurrent head and neck cancer squamous cell carcinoma and non-small cell lung cancer. It is administered through intravenous route. The therapeutic candidate comprises of autologous tumor infiltrating lymphocytes (TILs) isolated from the patient's tumor further expanded and then infused back to the patient enabling the patient robust immune response. |
| Mechanism of Action | Lifileucel (LN-144) comprises of patient's tumor infiltrating lymphocytes (TILs). TILs exhibit strong anti-tumor effector functions. When antigen-specific CD8+ T cells are exposed to processed antigens presented in association with human leukocyte antigen (HLA) class I proteins, they are activated. They expand clonally and differentiate. Differentiation process induces the formation of a large number of modified lysosomes loaded with lytic components such as perforin and several types of granzymes. In case of direct cell-cell interaction, activated CTLs |

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| | release lytic components leading to specific destruction of tumor cells expressing specific antigens. These components cause cell death by disruption of cell membrane and activation of the apoptotic pathway. CD4+ T cells respond to antigens presented by the HLA class II proteins expressed by antigen-presenting cells also mediate antitumor immunity. Natural killer cells express several ligands of the tumor necrosis factor family and can induce apoptosis of malignant cell targets. |
| ATC Classification | L01XL Antineoplastic cell and gene therapy |
| Drug Name | lifileucel (Marketed Drug) |
| Mechanism of Action | Lifileucel (LN-144) comprises of patient's tumor infiltrating lymphocytes (TILs). TILs exhibit strong anti-tumor effector functions. When antigen-specific CD8+ T cells are exposed to processed antigens presented in association with human leukocyte antigen (HLA) class I proteins, they are activated. They expand clonally and differentiate. Differentiation process induces the formation of a large number of modified lysosomes loaded with lytic components such as perforin and several types of granzymes. In case of direct cell-cell interaction, activated CTLs release lytic components leading to specific destruction of tumor cells expressing specific antigens. These components cause cell death by disruption of cell membrane and activation of the apoptotic pathway. CD4+ T cells respond to antigens presented by the HLA class II proteins expressed by antigen-presenting cells also mediate antitumor immunity. Natural killer cells express several ligands of the tumor necrosis factor family and can induce apoptosis of malignant cell targets. |
| ATC Classification | L01XL Antineoplastic cell and gene therapy |

## Patient Details

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| Age | **Minimum Age Eligibility** | **Maximum Age Eligibility** |
| | 18 Years | |
| Gender | Both | |
| Healthy Subject(s) | No | |
| Subject(s) Type | Adults, Advanced Disease, Asymptomatic, BRAF V600E Mutation, Cytotoxic/Antineoplastic/Anticancer Therapy Treated, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status | |
| Participant Criteria (Inclusion) | • Subjects with unresectable or metastatic melanoma (Stage IIIc or Stage IV)<br>• Subjects must have progressed following ≥ one prior systemic therapy | |

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| | including a programmed cell death protein-1 (PD-1) blocking antibody; and if proto-oncogene B-Raf (BRAF) V600 mutation-positive, a BRAF inhibitor or BRAF inhibitor in combination with mitogen-activated extracellular signal-regulated kinase (MEK) inhibitor<br>• At least one measurable target lesion, as defined by RECIST v1.1<br>  o Lesions in previously irradiated areas (or other local therapy) should not be selected as target lesions, unless treatment was ≥ 3 months prior to Screening, and there has been demonstrated disease progression in that particular lesion<br>• At least one resectable lesion (or aggregate of lesions resected) of a minimum 1.5 cm in diameter post-resection to generate TIL; surgical removal with minimal morbidity (defined as any procedure for which expected hospitalization is ≤ 3 days)<br>• Subjects must be ≥ 18 years of age at the time of consent. Enrollment of subjects > 70 years of age may be allowed after consultation with the Medical Monitor<br>• Subjects must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and an estimated life expectancy of ≥ 3 months<br>• In the opinion of the Investigator, subjects must be able to complete all study-required procedures<br>• Subjects must have the following hematologic parameters:<br>  o Absolute neutrophil count (ANC) ≥ 1000/$mm^3$<br>  o Hemoglobin (Hb) ≥ 9.0 g/dL<br>  o Platelet ≥ 100,000/$mm^3$<br>• Subjects must have adequate organ function:<br>  o Serum alanine transaminase (ALT)/serum glutamic-pyruvic transaminase (SGPT) and aspartate transaminase (AST)/serum glutamic-oxaloacetic transaminase (SGOT) ≤ 3 times the upper limit of normal (ULN); subjects with liver metastasis ≤ 5 times ULN<br>  o Estimated creatinine clearance (eCrCl) ≥ 40 mL/min using the Cockcroft-Gault formula<br>  o Total bilirubin ≤ 2 mg/dL<br>  o Subjects with Gilbert's syndrome must have a total bilirubin ≤ 3 mg/dL<br>• Subjects must have recovered from all prior therapy-related adverse events (AEs) to ≤ Grade 1 (per Common Terminology Criteria for Adverse Events [CTCAE] v4.03), except for alopecia or vitiligo, prior to Enrollment (tumor resection)<br>• Subjects with documented ≥ Grade 2 diarrhea or colitis as a result of previous treatment with immune checkpoint inhibitor(s) must have been asymptomatic for at least 6 months and/or had a normal colonoscopy |

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| | post-immune checkpoint inhibitor treatment, by visual assessment, prior to tumor resection<br>• Subjects must have a washout period ≥ 28 days from prior anticancer therapy(ies) to the start of the planned NMA-LD preconditioning regimen:<br><br>o Targeted therapy: MEK/BRAF or other targeted agent<br>o Chemotherapy<br>o Immunotherapy: anti-cytotoxic T lymphocyte-associated antigen 4 (CTLA-4)/anti-PD-1, other monoclonal antibody (mAb), or vaccine<br>o Palliative radiation therapy is permitted so long as it does not involve lesions being selected for TIL, or as target or non-target lesions. Washout is not required if all related toxicities have resolved to ≤ Grade 1 as per CTCAE v4.03<br>• Subjects of childbearing potential or their partners of childbearing potential must be willing to take the appropriate precaution to avoid pregnancy or fathering a child for the duration of the study and practice an approved, highly effective method of birth control during treatment and for 12 months after receiving the last protocol-related therapy<br><br>o Approved methods of birth control are as follows:<br>o Combined (estrogen and progesterone containing) hormonal birth control associated with inhibition of ovulation: oral, intravaginal, transdermal<br>o Progesterone-only hormonal birth control associated with inhibition of ovulation: oral, injectable, implantable<br>o Intrauterine device (IUD)<br>o Intrauterine hormone-releasing system (IUS)<br>o Bilateral tubal occlusion<br>o Vasectomized partner<br>o True sexual abstinence when this is in line with the preferred and usual lifestyle of the subject. Periodic abstinence (eg, calendar ovulation, symptothermal, post-ovulation methods) is not acceptable<br>• Subjects (or legally authorized representative) must have the ability to understand the requirements of the study, have provided written informed consent as evidenced by signature on an ICF approved by an Institutional Review Board/Independent Ethics Committee (IRB/IEC), and agree to abide by the study restrictions and return to the site for the required assessments, including the OS Follow-up Period<br>• Subjects have provided written authorization for use and disclosure of protected health information<br>• Subjects received anti-LAG3 therapy in the first-line setting, in the second- or later-line settings. Anti-LAG3 was combined with anti-programmed cell death protein 1 (PD-1) therapy, and with anti–PD-1 and |

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| | anti-cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) therapies<br>• Subjects received anti-LAG3 combination as the last therapy prior to lifileucel<br>• Subjects with tumor lesion/s for TIL generation and response assessment<br>• No limit on prior therapies or markers of tumor burden (Including size or LDH) |
| Participant Criteria (Exclusion) | • Subjects who have been shown to be BRAF mutation positive (V600), but have not received prior systemic therapy with a BRAF inhibitor alone or a BRAF inhibitor in combination with a MEK inhibitor<br>• Subjects who have received an organ allograft or prior cell transfer therapy<br>• Subjects with melanoma of uveal/ocular origin<br>• Subjects who have a history of hypersensitivity to any component or excipient of LN-144 or other study drugs:<br>o NMA-LD preconditioning regimen (cyclophosphamide, mesna, and fludarabine)<br>o Antibiotics (ABX) of the aminoglycoside group (ie, streptomycin, gentamicin); except those who are skin-test negative for gentamicin hypersensitivity<br>o Any component of the LN-144 infusion product formulation including dimethyl sulfoxide (DMSO), human serum albumin (HSA), IL-2, and dextran-40<br>• Subjects with symptomatic and/or untreated brain metastases (of any size and any number)<br>o Subjects with definitively treated brain metastases may be considered for Enrollment, and must be stable for ≥ 14 days prior to beginning the NMA LD preconditioning regimen<br>• Subjects who are on chronic systemic steroid therapy for any reason<br>• Subjects who have active medical illness(es) that would pose increased risk for study participation, including: active systemic infections requiring systemic ABX, coagulation disorders, or other active major medical illnesses of the cardiovascular, respiratory, or immune system<br>• Subjects who have any form of primary immunodeficiency (such as severe combined immunodeficiency disease [SCID] and acquired immunodeficiency syndrome [AIDS])<br>• Subjects who have a left ventricular ejection fraction (LVEF) < 45% or New York Heart Association (NYHA) functional classification > Class 1<br>• Subjects ≥ 60 years of age and who have a history of ischemic heart disease, chest pain, or clinically significant atrial and/or ventricular arrhythmias must have a cardiac stress test. subjects with any irreversible wall movement abnormalities are excluded<br>• Subjects who have a documented forced expiratory volume in 1 second |

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| | (FEV1) of ≤ 60%<br>• Subjects who have had another primary malignancy within the previous 3 years (with the exception of carcinoma in situ of the breast, cervix, or bladder; localized prostate cancer; and non-melanoma skin cancer that has been adequately treated)<br>• Subjects who have received a live or attenuated vaccine within 28 days of beginning the NMA-LD preconditioning regimen<br>• Subjects who are pregnant or breastfeeding<br>• Subjects whose cancer requires immediate attention or who would otherwise suffer a disadvantage by participating in this trial<br>• Subjects protected by the following constraints:<br>o Hospitalized persons without consent or persons deprived of liberty because of a judiciary or administrative decision<br>o Adult persons with a legal protection measure or persons who cannot express their consent<br>o Subjects in emergency situations who cannot consent to participate in the trial<br>• Subjects had Liver lesions, liver and/or brain lesions, target lesion<br>• Subjects had Anti–PD-1 / PD-L1 13 (100) Anti–CTLA-4, Anti–PD-1 + anti–CTLA-4 combination, BRAF ± MEK inhibitor<br>• Subjects with LDH level of ≤ULN 4, >1 to 2 × ULN 7, >2 × ULN |

**Biomarker Details**

| Biomarker Name | Biomarker Identifier | Biomarker Official Symbol | Biomarker Role |
|---|---|---|---|
| Aspartate Aminotransferase, Unspecified | GDBM0020752 | | Monitoring Treatment Safety |
| B-Raf proto-oncogene, serine/threonine kinase | GDBM0000193 | BRAF | Inclusion criteria |
| Bilirubin | GDBM0003206 | | Monitoring Treatment Safety |
| BRAF p.Val600 | GDBM0025514 | | Exclusion criteria; Inclusion criteria |
| C-X-C motif chemokine ligand 10 | GDBM0000876 | CXCL10 | Monitoring Treatment Response |
| CD274 Molecule | GDBM0002258 | CD274 | Inclusion criteria |
| L-Lactate Dehydrogenase | GDBM0003238 | | Inclusion criteria |
| Leukocytes | GDBM0003256 | | Monitoring Treatment Safety |

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| Lymphocytes | GDBM0013137 | | Monitoring Treatment Safety |
| Neutrophils | GDBM0003259 | | Monitoring Treatment Safety |
| Platelets | GDBM0003255 | | Monitoring Treatment Safety |
| Tumor Mutation Burden | GDBM0030685 | | Inclusion criteria |

| **Trial Results** | |
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| No. of Subjects Planned | 164 |
| No. of Subjects Enrolled | 181 |
| No. of Subjects Analyzed | 181 |
| Endpoint Classification | Efficacy, Pharmacodynamics, Safety |
| End Point Status | Achieved |
| Efficacy Results | **February 16, 2024**<br><br>Iovance's AMTAGVI (lifileucel) Receives U.S. FDA Accelerated Approval for Advanced MelanomaBased on the results announced by Iovance Biotherapeutics, Inc in the press release, GlobalData inferred that AMTAGVI demonstrated deep and durable responses. Among the 73 subjects from Cohort 4 who received the recommended AMTAGVI dose from an approved manufacturing facility, 31.5% achieved an objective response by Response Evaluation Criteria in Solid Tumors (RECIST 1.1) with a median duration of response not reached at 18.6 months follow-up (43.5% of responses had a duration greater than 12 months). Among the 153 subjects from Cohort 4 and Cohort 2, 31.4% achieved an objective response by RECIST 1.1 with a median duration of response not reached at 21.5 months follow-up (54.2% of responses had a duration greater than 12 months).https://ir.iovance.com/news-releases/news-release-details/iovances-amtagvitm-lifileucel-receives-us-fda-accelerated<br><br>**December 06, 2023**<br><br>Presented at the European Society for Medical Oncology Immuno-Oncology Annual Congress (ESMO IO 2023), December 06 - 08, 2023, Geneva, Switzerland Long-term Efficacy and Patterns of Response of Lifileucel Tumor-infiltrating Lymphocyte (Til) Cell Therapy in Patients with Advanced Melanoma: A 4-year Analysis of the C-144-01 Study Session: Proffered Paper session 2 Abstract No.: 119O Martin Wermke et al.Based on the results presented, GlobalData inferred that independent review committee-assessed ORR by |

RECIST v1.1 was 31.4% with median DOR (months) of NR. The 1-, 2-, 3-, and 4-year OS rate was 54.0%, 33.9%, 28.4%, and 21.9%, respectively. Responders (n=48) had a median age of 55.0 years with median of 3 prior lines of therapies. Clinically meaningful 4-year overall survival(OS) rates were seen across all patterns of response (range, 37.2%–68.2%), subjects with deepened response had numerically higher OS rate. Findings:

| | **Early responders[a] (n=39)** | **Late responders[b] (n=9)** | **Responders with deepened response[c] (n=16)** | **Responders without deepened response (n=32)** | **All responders (n=48)** |
|---|---|---|---|---|---|
| OS rate at 4 y, % (95% CI) | 48.3 (31.9, 62.9) | 41.7 (10.9, 70.8) | 68.2 (39.5, 85.4) | 37.2 (21.0, 53.5) | 47.3 (32.5, 60.7) |
| Median DOR, mo (95% CI) | NR (6.1, NR) | 19.8 (4.1, NR) | NR (8.3, NR) | 26.2 (4.1, NR) | NR (8.3, NR) |

[a]Subjects with CR or PR on Day 42 visit. [b]Subjects with CR or PR after Day 42 visit. [c]Subjects who had SD and improved to confirmed PR or had PR and improved to confirmed CR. CI, confidence interval, CR, complete response, DOR, duration of response; OS, overall survival; PR, partial response, SD, stable disease. https://cslide.ctimeetingtech.com/immuno23hybrid/attendee/confcal/show/session/10

**November 16, 2023**

Iovance Biotherapeutics Announces Clinical Data for Lifileucel in Advanced Mucosal Melanoma at the European Society for Medical Oncology (ESMO) CongressBased on the results announced by Iovance Biotherapeutics Inc., in the press release, GlobalData inferred that 12 subjects with advanced mucosal melanoma treated with lifileucel had progressed on or after immune checkpoint inhibitor therapy. Subjects with mucosal melanoma, which is rare and difficult to treat, have worse outcomes after anti–PD-1 therapy compared to subjects with other melanoma subtypes. Lifileucel was clinically meaningful and durable with the rare and difficult-to-treat mucosal melanoma subtype. The objective response rate (ORR) assessed by an independent review committee (IRC) using RECIST v1.1 was 50% (95% CI: 21%–79%). At median study follow-up of 35.7 months, median duration of response (DOR) was not reached (NR; 95% CI: 12.5 months–NR), median progression free survival (PFS) was NR (95% CI: 1.4 months–NR), and median overall survival (OS) was 19.4 months (95% CI: 7.9 months–NR).

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| | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-clinical-data-lifileucel-1<br><br>**November 01, 2023**<br><br>Presented at the 38th Virtual Annual Meeting and Pre-Conference Programs of the Society for Immunotherapy of Cancer (SITC 2023), November 01 - 05, 2023, San Diego, California, USA Long-term Efficacy and Safety of Lifileucel Tumor-infiltrating Lymphocyte (Til) Cell Therapy in Patients with Advanced Melanoma: A 4-year Analysis of the C-144–01 Study<br>Session: Clinical Trial In Progress<br>Abstract No.: 776 Theresa Medina et al.Based on the results presented, GlobalData inferred that the median overall survival (OS) was 13.9 months (95% CI: 10.6 to 17.8). One-, 2-, 3-, and 4-year overall survival(OS) rate was 54.0%, 33.9%, 28.3%, and 22.2%, respectively. Forty-eight of 153 (31.4%) lifileucel-treated subjects achieved an investigator-assessed objective response, 54.2%, 39.6%, 33.3%, and 20.8% of responses lasted ≥12, ≥24, ≥36, and ≥48 months, respectively. Twelve responses (25.0%) were ongoing at time of analysis and longest response was ongoing at 59.9 months. These promising results continue to show favorable survival outcomes, durable responses.https://jitc.bmj.com/content/11/Suppl_1/A873<br><br>**October 20, 2023**<br><br>Presented at the European Society for Medical Oncology Congress (ESMO 2023), October 20-24, 2023, Madrid, Spain<br><br>Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy in Patients (Pts) with Advanced Mucosal Melanoma after Progression on Immune Checkpoint Inhibitors (ICI): Results from the Phase II C-144-01 Study<br>Session: Mini Oral session<br>Abstract No.: 1086MO<br><br>Evidio Domingo-Musibay et al.Based on the results presented, GlobalData inferred that 12 subjects were analyzed in the study. The objective response rate (confirmed responses) was 50% (6/12; 95% CI: 21%-79%). At median study follow-up of 35.7 months, median duration of response was not reached (NR; 95% CI: 12.5 months-NR), median progression-free survival was NR overall survival was 19.4 months (95% CI: 7.9-NR). Four of six responders had durable and ongoing responses at the time of the datacut. Mucosal melanoma showed a low tumor mutational burden compared with cutaneous melanoma. Mean tumor mutational burden of mucosal versus cutaneous melanoma was 2.145 mut/Mb versus 10.47 mut/Mb, respectively. The tumor-infiltrating lymphocyte persistence was similar in subjects with mucosal or cutaneous melanoma through month 12. |

**Findings:**

| Parameters | Mucosal Melanoma (N=12) |
|---|---|
| **Best Overall Response** | |
| CR | 1 (8.3) |
| PR | 5 (41.7) |
| SD | 4 (33.3) |
| PD | 2 (16.7) |
| **DOR, n (%)** | |
| >6 months | 6/6 (100) |
| >12 months | 5/6 (83.3) |
| >24 months | 4/6 (66.7) |

https://www.iovance.com/uploads/ESMO_2023_C-144-01-Mucosal_Sub_Analyses_Final-002-2562-publication.pdfhttps://cslide.ctimeetingtech.com/esmo2023/attendee/confcal/presentation/list?q=1086MO&r=st%7E9

**April 23, 2023**

Presented at the 49th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023), April 23 - 26, 2023, Paris, France
Efficacy and Safety of Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy in Patients with Advanced Melanoma Enrolled in Consecutive Cohorts of the C-144-01 Study
Session: Cellular Therapies other than CARs
Abstract No.: P223 Larkin J et al.Based on the results presented, GlobalData inferred that objective response rate (ORR) was 31.4% (5.9% complete response (CR), 25.5% partial response (PR)). Multivariable analyses adjusted for ECOG PS showed elevated LDH and target lesion sum of diameters (SOD) >median were correlated with ORR (p=0.008); normal LDH and SOD <median were associated with higher odds of response than either (OR=2.08) or both (OR=4.42) risk factors. At a median follow-up of 36.5 months, median DOR was not reached ((NR); 95% CI: 8.3 months to NR); 41.7% of responses lasted ≥24 months. Median overall survival (OS) was 13.9 months (95% CI: 10.6 to 17.8) and response to lifileucel was associated with a 73.4% reduced risk of death compared with non-response (HR=0.266; p<0.0001). In a landmark analysis at 1.5 months post-infusion, median OS was NR among those with a response at this time. Median number of IL-2 doses was 6. In subjects receiving 1–2, 3–4 and 5–6 IL-2 doses, ORR was 37.5%, 30.8% and 31.2% (p=0.87) and duration of response (DOR) was ≥12 months in 66.7%, 75.0% and 47.1% of responders (Cox regression p=0.25), respectively. ORR was 40% in 5 patients who progressed after prior high-dose IL-2 therapy in the metastatic

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| | setting. https://ebmt2023.abstractserver.com/program/#/details/presentations/963<br><br>**March 25, 2023**<br><br>Presented at the 2023 International Conference on Surgical Cancer Care (SSO 2023), March 22 - 25, 2023, Boston, Massachusetts, USA Lifleucel TIL Cell Therapy in Patients with Advanced Melanoma After Progression on Immune Checkpoint Inhibitors (ICI) Andbtargeted Therapy: Tumor Tissue Procurement Data from the C-144-01 Study<br>Abstract No.: 64 Michael E Egger et al.Based on the results presented, GlobalData inferred that a total of 153 subjects were analyzed in this study. The target lesion sum of diameter reductions were observed regardless of tumor-infiltrating lymphocyte (TIL) dose. The objective response rate (ORR) was 31% (8 complete response, 40 partial response), with responses observed across all resection sites. The median duration of response was not reached.https://link.springer.com/content/pdf/10.1245/s10434-023-13332-7.pdf?pdf=inline%20link<br><br>**February 15, 2023**<br><br>Presented at the 2023 Transplantation & Cellular Therapy (TCT 2023) Meetings, February 15 - 19, 2023, Orlando, Florida, USA Response to Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy after ICI Resistance Regardless of Definition: An Analysis of the C-144-01 Trial in Patients with Advanced Melanoma<br>Session: Poster Session: Engineered Immune Cells (CAR-T, NK, TCR): Clinical - Immune Effector Cells for Heme Malignancies<br>Abstract No.: 290 Amod Sarnaik et al.Based on the results presented, GlobalData inferred that in primary resistant subjects, overall response rate (ORR) with lifileucel was 33% (95% CI: 24%, 43%) and median duration of response(DOR) was not reached (NR; 95% CI: 12.5 months(mo), NR). In primary refractory subjects, ORR was 31% (95% CI: 22%, 42%) and median DOR was NR (95% CI: 15.1 mo, NR). No significant difference was found in T-cell receptor (TCR) clonality, tumor mutational burden (TMB), or immune-related signatures between primary resistant/refractory and non-primary resistant/refractory tumors. A substantial overlap was observed in immune-related signatures in primary resistant/refractory and non-primary resistant/refractory subjects, with similar response rates. IFN alpha signature expression scores trended higher in primary resistant/refractory responders than non responders. Beta-2 microglobulin deletions were detected only in primary resistant/refractory non responders.https://astct-29-s2.elsevierdigitaledition.com/<br><br>**December 08, 2022**<br><br>Presented at the European Society for Medical Oncology Immuno-Oncology Annual Congress (ESMO IO 2022), December 07 - 09, 2022, Geneva, |

Switzerland Number of IL-2 doses and clinical outcomes of tumor-infiltrating lymphocyte (TIL) cell therapy: Post hoc analysis of the C-144-01 trial of lifileucel in patients with advanced melanoma
Session: Mini Oral session 1
Abstract No.: 35MO Jessica Hassel et al.Based on the results presented, GlobalData inferred that ORR to lifileucel was 38%, 31%, and 31% in subjects receiving 1–2, 3–4, and 5–6 doses, respectively (p=0.87); 67%, 75%, and 47% of responders had DOR ≥12 months (Cox regression p=0.39). ORR was 40% in 5 subjects who progressed after prior high-dose IL-2 monotherapy.https://oncologypro.esmo.org/meeting-resources/esmo-immuno-oncology-congress/number-of-il-2-doses-and-clinical-outcomes-of-tumor-infiltrating-lymphocyte-til-cell-therapy-post-hoc-analysis-of-the-c-144-01-trial-of-lifileuc

**November 10, 2022**

Iovance Biotherapeutics Inc., "Investor Event & KOL Roundtable Presentation (Slide No: 08-19)", Nov 2022Based on the results reported, GlobalData inferred that lifileucel is effective. Objective Response Rate (ORR): 31.4% IRC-assessed ORR was observed. 91% concordance rate between IRC- and investigator-assessed ORR were reported in the study. Median time from resection to lifileucel infusion was 33 days.

| | **Cohort 2 (n=66)** | **Cohort 4 (n=87)** | **Cohort 2+4 (N=153)** |
|---|---|---|---|
| **ORR, n (%)** | **23 (34.8)** | **25 (28.7)** | **48 (31.4)** |
| (95% CI) | (23.5, 47.6) | (19.5, 39.4) | (24.1, 39.4) |
| **Best overall response, n (%)** | | | |
| CR | 5 (7.6) | 4 (4.6) | 9 (5.9) |
| PR | 18 (27.3) | 21 (24.1) | 39 (25.5) |
| SD | 24 (36.4) | 47 (54.0) | 71 (46.4) |
| Non-CR/Non-PD | 1 (1.5) | 0 | 1 (0.7) |
| PD | 15 (22.7) | 12 (13.8) | 27 (17.6) |
| Nonevaluable | 3 (4.5) | 3 (3.4) | 6 (3.9) |

Reduction of tumor burden in 79.3% (111/140) of subjects were observed. Univariable and Multivariable Analyses of ORR: Response to Lifileucel observed across all subgroups were analyzed. In adjusted (ECOG PS) multivariable analyses, LDH and target lesion sum of diameters (SOD; tumor mass across locations) were correlated with ORR (P=0.008) - subjects with normal LDH and SOD. Time to Response, Duration of Response, and Time on Efficacy Assessment for Confirmed Responders: Median time from lifileucel infusion to best response was 1.5 months. Responses deepened over time: 7 subjects (14.6%) initially assessed as PR were later confirmed CR, 4 subjects (8.3%) converted to

CR >1 year post-lifileucel infusion; 2 (4.2%) of these 4 subjects converted after 2 years. Best response of 10 subjects (20.8%) improved from SD to PR. 35.4% of responses ongoing as of data cutoff. Duration of Response: Median DOR was not reached at median study follow up of 36.5 months. 41.7% of responses continued for ≥24 months.

| | **Cohort 2 (n=23)** | **Cohort 4 (n=25)** | **Cohort 2+4 (N=48)** |
|---|---|---|---|
| Median follow up, months | 45.1 | 33.0 | 36.5 |
| 95% CI | (44.2, 51.4) | (30.4, 35.2) | (34.7, 44.2) |
| Median DOR, months | NR | 10.4 | NR |
| 95% CI | (NR, NR) | (4.1, NR) | (8.3, NR) |
| Min, max (months) | 1.4+, 54.1+ | 1.4+, 34.3+ | 1.4+, 54.1+ |
| **DOR ≥12 months, n (%)** | **15 (65.2)** | **11 (44.0)** | **26 (54.2)** |
| **DOR ≥24 months, n (%)** | **11 (47.8)** | **9 (36.0)** | **20 (41.7)** |

Overall Survival by response at 6 Weeks after lifileucel infusion: mOS was not reached in in a landmark analysis in subjects who achieved response at first assessment (6 weeks post-lifileucel infusion).

| | **Median OS (months), by response at 6 weeks** | **95% CI** |
|---|---|---|
| **Responders** | NR | 30.4, NR |
| **Non-responders** | 10.3 | 6.8, 13.1 |
| **Log-rank p-value** | **<0.0001** | **<0.0001** |

Overall Survival: mOS was 13.9 Months and 12-Month OS Rate was 54.0% (95% CI: 45.6%, 61.6%).

| | **Cohort 2 (n=66)** | **Cohort 4 (n=87)** | **Cohort 2+4 (N=153)** |
|---|---|---|---|
| Median OS, months | 15.6 | 12.7 | **13.9** |
| 95% CI | (11.0, 23.3) | (8.3, 17.8) | **(10.6, 17.8)** |

https://ir.iovance.com/static-files/b668e3af-7748-41d2-9b58-29108038a59c

**November 08, 2022**

Presented at the hybrid 37th Annual Meeting Pre-Conference Programs of the Society for Immunotherapy of Cancer's (SITC 2022), November 8 – 12, 2022, Boston, Massachusetts, United states Lifileucel TIL cell monotherapy in patients with advanced melanoma after progression on immune checkpoint inhibitors (ICI) and targeted therapy: pooled analysis of consecutive cohorts (C-144–01 study)

Session: Clinical Trials In Progress
Abstract No.: 789 Amod Sarnaik et al.Based on the results presented, GlobalData inferred that objective response rate was 31% (95% confidence interval: 24.1%-39.4%) (C2: 35%, C4: 29%), with 8 complete responses and 40 partial responses. At median study follow-up of 27.6 months, median duration of response was not reached (NR) and forty-two percent of responses extended ≥18 months, and 40% (19/48) of responses were ongoing at time of data cut. In multivariable analyses adjusted for ECOG PS, elevated LDH and target lesion SOD >median were independently correlated with objective response rate (P=0.008), normal LDH and SOD < median were associated with higher odds of response than either (OR=2.08) or both (OR=4.42) risk factors. The median overall survival was 13.9 months (95% confidence interval: 10.6-17.8 and in an analysis of survival by response at first assessment (1.5 months post-lifileucel infusion), median overall survival in responders was not reached (95% CI: 22.5 months-NR).https://jitc.bmj.com/content/10/Suppl_2/A821

**September 10, 2022**

Presented at the Virtual European Society for Medical Oncology Congress (ESMO 2022), September 09 - 13, 2022, Paris, France Efficacy and Safety of Lifileucel, an Investigational Autologous Tumor-infiltrating Lymphocyte (TIL) Cell Therapy, in Patients with Advanced Melanoma Previously Treated with Anti-LAG3 Antibody
Session: Poster session 3
Abstract No.: 844P J J. Larkin et al.Based on the results presented, GlobalData inferred that objective response rate for lifileucel was 38.5% (five partial responses), three responders had primary and two acquired resistance to anti-LAG3 + anti–PD-1. Responses were durable, with 60% of responses extending beyond 12 months.

| **Investigator-Assessed Response, n (%)** | **N=13** |
|---|---|
| Objective response rate | 5 (38.5) |
| Best overall response | |
| Complete response | 0 |
| Partial response | 5 (38.5) |
| Stable disease | 5 (38.5) |
| Progressive disease | 3 (23.1) |

In all responders, first response was recorded <3 months after lifileucel infusion. Three of 5 (60%) responses extended beyond 12 months, with 1 >response still ongoing at time of data cutoff. Median duration of response was 13.4 months (95% CI, 4.8, NR). Three responders had primary and 2 had acquired anti-LAG3 resistance. A subject (C4-07) who achieved best response of partial response presented with a chest wall muscle target lesion that measured ~25.4 × 17.5 mm at baseline and showed 75% reduction at week 6 and 100% reduction at week 12.

| | |
|---|---|
| | Subjects with best overall response of partial trended to show greater polyclonality (lower Simpson Clonality) numerically in pre-infusion blood, autologous tumor-infiltrating lymphocyte (TIL) infusion product, and post-infusion compared with subjects achieving stable disease or progressive disease. A numerically higher percentage of shared TCR repertoire between the TIL infusion product and tumor sample was observed in the responders (n=3) than in the non-responders (n=3) (p=0.03). Responses were observed in subjects with both primary and acquired anti-LAG3 resistance, suggesting that lifileucel outcomes may not be affected by prior anti-LAG3 treatment. https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdfhttps://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano<br><br>**June 09, 2022**<br><br>Presented at the Jefferies 2022 Annual Global Healthcare Conference, June 08 - 10, 2022, New York, USABased on the results presented, GlobalData inferred that 44% of responders with duration of response ≥12 months. The longest ongoing response was 26.3 months. 83% of full analysis set prior anti-CTLA-4. 55% of full analysis set prior anti-CTLA-4 in combination with anti-PD-1.https://wsw.com/webcast/jeff240/iova/1845375<br><br>**June 06, 2022**<br><br>Presented at the 58th Annual Meeting of American Society of Clinical Oncology (ASCO 2022), June 03 - 07, 2022, Chicago, Illinois, USA Tumor Mutational Burden (TMB) in Immune Checkpoint Inhibitor (ICI)-naïve and -experienced Patients with Metastatic Melanoma Treated with Lifileucel, a Tumor-infiltrating Lymphocyte (TIL) Cell Therapy<br>Session: Melanoma/Skin Cancers<br>Abstract No.: 9524 Harriet M Kluger et al. Based on the pooled results of NCT03645928 and NCT02360579 presented, GlobalData inferred that 21 subjects in C2 were included in the case-control study and had objective response rate (ORR) of 38.1%. The percentage of subjects with high tumor mutational burden (TMB) was 19.0% in C2 (P = 0.1). ORR in the low and high TMB groups was 41.1% and 25.0% in C2; 12.5% in C2 had high TMB. In logistic regression analysis adjusted for cohort, TMB was not associated with response to lifileucel (P=0.8).<br><br>The efficacy (ORR) of lifileucel may be independent of TMB, regardless of treatment setting, consistent with its proposed immune checkpoint pathway-independent mechanism of action. The percentage of subjects with high tumor mutational burden tended to be lower in tumors with prior immune checkpoint inhibitor (ICI) exposure than in those that were ICI-naïve. |

| | |
|---|---|
| | https://meetings.asco.org/abstracts-presentations/210188<br><br>**May 26, 2022**<br><br>Ovance Biotherapeutics Announces Positive Clinical Data for Lifileucel in Advanced MelanomaBased on the results announced by Lovance Biotherapeutics Inc in the press release, GlobalData inferred that in Cohort 4 (n=87), the objective response rate (ORR) by an independent review committee (IRC) using RECIST 1.1 criteria was 29% (95% confidence interval (CI): 19.5%, 39.4%) with three complete responses and 22 partial responses. The median duration of response (DOR) in Cohort 4 by IRC was 10.4 months with a median study follow-up of 23.5 months. These data demonstrate that one-time treatment with lifileucel therapy may provide meaningful benefit in heavily pre-treated patients. Cohort 4's findings are supported by Cohort 2 (n=66), where the ORR by IRC was 35% (95% CI: 23.5%, 47.6%) with five complete responses and 18 partial responses. The median DOR in Cohort 2 was not reached with a median study follow-up of 36.6 months. The ORR by IRC for pooled patients (n=153) from both Cohorts 2 and 4 was 31% (95% CI: 24.1%, 39.4%) and median DOR was not reached at a median study follow up of 27.6 months. patients in Cohort 4 exhibited higher baseline disease burden in comparison to patients in Cohort 2, including a substantially higher proportion of patients with elevated baseline lactate dehydrogenase (LDH) levels, a well-known negative prognostic factor (64.4% versus 40.9%), as well as a greater number of tumor lesions at baseline (83.9% versus 65.2% with more than three lesions). In addition, patients in Cohort 2 also had approximately half the cumulative duration of anti-PD-1 therapy before lifileucel therapy in comparison to patients in Cohort 4. Reduced duration of prior anti-PD-1 therapy was shown to be associated with an increase of DOR to lifileucel. https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data<br><br>**January 12, 2022**<br><br>Presented at the Virtual 40th Annual J.P. Morgan Healthcare Conference, January 10 - 13, 2022, San Francisco, California, USA Based on the results presented, GlobalData inferred that with 33.1 months median study follow-up responses continue to deepen over time. In chorot 2, 17% of subjects reported deepening of response and one partial response converted to complete response (CR) with 24 months post-lifileucel.https://ir.iovance.com/static-files/3f991737-1354-441b-9ba2-e4231f1fb3d5<br><br>**May 29, 2020** Iovance Presents Updated Clinical Data for Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel in Advanced Melanoma at ASCO Scientific Program Based on the results announced by Iovance Biotherapeutics Inc, in the press release, GlobalData inferred that the median duration of response has not been reached at 18.7 months of median study follow up (2.2 to 26.9+ months) supporting potential benefit of the one-time treatment of lifileucel TIL |

therapy in advanced melanoma subjects. 36.4% overall response rate (ORR) maintained. The latest data at ASCO also demonstrate durable responses with lifileucel across the broad spectrum of our study population, including a wide age range of metastatic melanoma subjects who have received prior anti-CTLA-4 and BRAF targeted treatments, and equally in subjects with PD-L1 high and low status. The preliminary results of the C-144-01 study demonstrate that autologous tumor infiltrating lymphocytes (TILs; lifileucel) induce durable clinical responses in a significant percentage of this moribund population. The lifileucel shows a 36.4% overall response rate (2 complete responses and 22 partial responses) and a disease control rate of 80% (n=66). They have progressed on multiple prior therapies (3.3 mean prior therapies), including anti-PD-1 and BRAF/MEK inhibitors. https://ir.iovance.com/news-releases/news-release-details/iovance-presents-updated-clinical-data-tumor-infiltrating **May 20, 2020** Long-term follow up of lifileucel (LN-144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advanced melanoma progressed on multiple prior therapies Amod Sarnaik et al Journal of Clinical Oncology, Volume 38, Issue 15, Pages 10006-10006, 2020 Based on the results reported, GlobalData inferred that the ORR by investigator was 36.4% (2 CR, 22 PR) and DCR was 80.3%. The mean time to response was 1.9 months (range: 1.3-5.6). After a median study follow-up of 17.0 months, median DOR (mDOR) was still not reached. Six responders have progressed, 2 have died and 2 started other anti-cancer therapy without progression.
https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.10006 **June 2017**

Presented at the 53rd American Society of Clinical Oncology Annual Meeting (ASCO 2017), June 02-06, 2017, Chicago, Illinois, USA

Efficacy of single administration of tumor-infiltrating lymphocytes (TIL) in heavily pretreated patients with metastatic melanoma following checkpoint therapy
Category: Developmental Therapeutics—Immunotherapy
Abstract No.: 3045

Amod Sarnaik et al.

Based on the preliminary results presented, GlobalData inferred that a total of nine subjects were analyzed in this study Responses were seen in subjects with tumors carrying wild type or BRAF mutations. All subjects showed persistence of tumor-infiltrating lymphocytes on day 14 post-infusion. **Findings:**

| **Observations** | **Observed values** |
|---|---|
| Overall Response Rate (ORR), % | 33 |
| Complete Response (CR), % | 11 |
| Partial response, (PR), % | 22 |
| Stable Disease (SD), % | 22 |

| | |
|---|---|
| Progressive disease (PD),% | 33 |
| NE,% | 11 |
| Mean time to best response, months | 3.6 |
| Median duration of follow up, months | 3.6 (1.1+, 12.1) |

http://abstracts.asco.org/199/AbstView_199_185466.html **June 05, 2017** Lion Biotechnologies Announces Updated Data at 2017 American Society of Clinical Oncology (ASCO) Annual Meeting from Ongoing LN-144 Phase 2 Clinical Trial Based on the results announced by Lion Biotechnologies, Inc. in the press release, GlobalData inferred that a total of 16 subjects were analyzed in the first cohort. Data demonstrated clinically-significant outcomes, as assessed both by ORR and DCR, in a heavily pre-treated subjects group, all of which received prior anti-PD-1 and over 80% with prior anti-CTLA-4 checkpoint inhibitors. Of the evaluable subjects, a 29% objective response rate was observed including one complete response (CR) continuing beyond 15 months post-administration of a single tumor-infiltrating lymphocytes treatment. A total of 77% of subject had decline in target tumor size. Mean time to first response was 1.6 months, with the CR developed at month 6. Responses were seen in subjects with tumors carrying wild type or BRAF mutations. http://www.marketwired.com/press-release/lion-biotechnologies-announces-updated-data-2017-american-society-clinical-oncology-nasdaq-lbio-2220056.htm **June 29, 2017** GlobalData Primary Research from Insights Based on the results presented, GlobalData inferred that one subject who demonstarted partial response, died after six months. **June 06, 2017**

Presented at the Jefferies 2017 Global Healthcare Conference, June 06-09, 2017, New York, USA

Based on the results presented, GlobalData inferred that a total of 14 subjects were analyzed during the study.

| **Parameter** | **Observation, n(%)** |
|---|---|
| Objective response rate | 4 (29) |
| Disease control rate | 9(64) |
| Complete response | 1 (7) |
| Partial response | 3 (21) |
| Stable disease | 5(36) |
| Progressive disease | 4 (29) |
| Non-evaluable | 1 (7) |

http://wsw.com/webcast/jeff105/lbio/?lobby=true&day=1 (Slides 12,17,18,19,20,21,22,23,24,25,37)

**December 10, 2017** Iovance Biotherapeutics Inc Investor and Analyst Day Presentation Based on the results presented, GlobalData inferred that 10 subjects

were analyzed in the study.

| Response | Paitents, N=10 n (%) |
|---|---|
| Objective response rate | 4 (40) |
| Disease control rate | 8 (80) |
| Partial response | 4 (40) |
| Stable disease | 4 (40) |
| Progressive disease | 1 (10) |
| Non-evaluable | 1 (10) |

https://edge.media-server.com/m6/p/fhqnhyoj (Slide no: 28) **December 2017** Presented at 2018 ASCO Gastrointestinal (GI) Cancers Symposium (ASCO GI 2018), January 18 - 20, 2018, San francisco, CA, USA Novel cryopreserved tumor infiltrating lymphocytes (LN-144) administered to patients with metastatic melanoma demonstrates efficacy and tolerability in a multicenter Phase 2 clinical trial
Session: Late-Breaking Abstracts - Poster presentations - Cellular Therapy Approaches
Abstract No.: P515 Amod Sarnaik et al.

Based on the results presented, GlobalData inferred that the anti-tumor activity was observed including partial responses to the tumor infiltrating lymphocytes (TIL) therapy in subjects treated in cohort 2.
https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-017-0297-3?site=jitc.biomedcentral.com **October 11, 2018** Iovance Biotherapeutics Reports Results from FDA End of Phase 2 meeting and Provides Updates About the Company's Clinical Program

Based on the results announced by Iovance Biotherapeutics Inc., in the press release, GlobalData inferred that 37% objective response rate demonstrated in 46 metastatic melanoma subjects previously treated with a PD-1 blocking antibody if BRAF mutation positive, BRAF inhibitor with duration of response ranging from 1.3+ to 14+ months.

Approximately 31% objective response rate in 13 recurrent metastatic squamous cell carcinoma of head and neck cancer subjects and 27% objective response rate in 15 recurrent, metastatic or persistent cervical carcinoma subjects. Objective response rate observed in one complete response and 16 partial responses, six of which are unconfirmed and pending subject upcoming second assessments.

http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2371343

**November 2018**

Presented at the 33rd Annual Meeting and Pre-Conference Programs of the Society for Immunotherapy of Cancer (SITC 2018), November 07 - 11, 2018, Washington, D.C, USA

Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients following progression on checkpoint inhibitors
Session: Clinical Trials (In Progress)
Abstract No.: O22

Amod Sarnaik et al.

Based on the preliminary results presented, GlobalData inferred that a total of 30 subjects were analyzed in this study.

**Findings for cohort 2:**

| **Parameter** | **Observed values** |
|---|---|
| Objective response rate (%) | 33 |
| uCR (n) | 1 |
| PR (n) | 7 |
| uPR (n) | 2 |
| DCR (%) | 73 |
| Median time to initial response (months) | 1.7 (1.6-4.4) |
| Median DOR | Not reached |

A longer follow-up led to improved response in few subjects including complete response. Lifileucel-induced in vitro IFNγ response to the antibody coated beads (anti-CD3, anti-CD28, anti-CD137) and serum IP-10 levels of post-treatment, correlates with decrease in tumor (Sum of Diameter of target lesions) and/or overall response.

https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-018-0423-x (Pages 385-386)

**November 06, 2018**

Iovance Biotherapeutics Announces Updated Phase 2 Clinical Data from the Lifileucel Metastatic Melanoma Trial at the Society for Immunotherapy of Cancer's 33rd Annual Meeting

Based on the results announced by Iovance Biotherapeutics Inc., in a press release, GlobalData inferred that 47 subjects were analyzed in this study.

Objective response rate was 38% from 47 consecutively dosed metastatic

melanoma subjects, including complete response was one and partial responses were 17, four of which are unconfirmed as of October 25, 2018, pending these subjects' upcoming second assessments. A median duration of response was 6.4 months (1.3+ - 14+ months). All subjects were unsuccessfully treated with the prior anti-PD-1 therapy.

http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2375545 **November 09, 2018** Iovance Biotherapeutics Inc Clinical Program Update Presentation Based on the results presented, GlobalData inferred that Lifileucel was effective.

| **RESPONSE** | **PATIENTS, N=47** |
|---|---|
| | n (%) |
| Objective Response Rate | 18 (38%) |
| Complete Response | 1 (2%) |
| Partial Response (PR+ uPR') | 17 (36%) |
| Stable Disease | 18 (38%) |
| Progressive Disease | 7 (15%) |
| Non-Evaluable | 4 (9%) |
| Disease Control Rate | 36 (77%) |

72% of subjects showed reduction in tumor burden. 16 out of 17 subjects had no response to prior anti-PD-1.

phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAxNzc0fENoaWxkSUQ9NDEzNTM2fFR5cGU9MQ==&t=1

**January 10, 2019**

Presented at the 37th Annual J.P. Morgan Healthcare Conference, January 07 - 10, 2019, San Francisco, California, USA

Based on the results presented, GlobalData inferred that cohort 2 showed 38% objective response rate in 47 subjects, median duration of response was 64% and disease control rate (DCR) was observed in 77% subjects.

All responders were greater than 30%.

http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1(Slide 04)

**March 1, 2019** Presented at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium (ASCO SITC 2019), February 28 - March 2, 2019, San Francisco,

California, USA Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients previously treated with at least one prior systemic therapy
Session: Poster Session B
Abstract No.: 136 Amod Sarnaik et al, Based on the preliminary results presented, GlobalData inferred that a total of 47 subjects were analyzed in this study.Improved response was observed in subjects at long term follow-up in subjects which included complete response. LN-144 was effective in subjects with metastatic melanoma. **Findings**

| **Parameter** | **Observation** |
|---|---|
| Overall response rate | 38 |
| Complete response | 1 |
| Partial response | 13 |
| uPR | 4 |
| Duration of response | 6.4 (1.3 -13.7) |

https://meetinglibrary.asco.org/record/170363/abstract

**April 01, 2019**

Presented at the 110th Annual Meeting of American Association for Cancer Research (AACR 2019), March 29 - April 03, 2019, Atlanta, Georgia, USA

Persistence of cryopreserved tumor-infiltrating lymphocyte product lifileucel (LN-144) in C-144-01 study of advanced metastatic melanoma
Session: Session LBPO.IM01 - Late-Breaking Research: Immunology 1
Abstract No.: LB-069 / 14

Viktoria Gontcharova et al.

Based on the results presented, GlobalData inferred that comparable percentages of Shared uCDR3 have been detected in responders and non-responders.

The majority of Shared uCDR3 were not detected in the subjects peripheral blood at the time of enrolment, indicating that they represented intratumoral clonotypes that persisted after TIL administration.

Shared uCDR3 clones were represented at either high or low frequencies in the TIL product could persist for at least six weeks post-infusion.

Greater than 97% of persisting clones were uniquely present in individual responding and non-responding subjects, indicating a unique repertoire in each TIL preparation.

| | |
|---|---|
| | https://www.abstractsonline.com/pp8/#!/6812/presentation/9204<br><br>**April 01, 2019**<br><br>Iovance Biotherapeutics Presents Data at AACR Annual Meeting on T-Cell Diversity and Persistence in Patients Receiving Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel<br><br>Based on the results announced by Iovance Biotherapeutics, Inc., in the press release, GlobalData inferred that all subjects in cohort 2 demonstrated circulation at 42 days post-infusion was persistent.<br><br>Each subject had a unique TIL product with almost no overlap between subjects for expanding clones in the human body observed post-infusion. The small number of overlapping clones between a few subjects was not associated with a clinical response. This uniqueness in clonal profiles associated with response highlights the challenge of identifying a few T cell receptors as mediators of activity and supports using a polyclonal product such as the Iovance bulk TIL to treat high mutational load solid tumors.<br><br>http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2392939 **May 15, 2019**<br><br>Iovance Biotherapeutics Announces Updates to Tumor Infiltrating Lymphocyte (TIL) Therapy Clinical Programs<br><br>Based on the results announced by the Iovance Biotherapeutics, Inc., in the press release, GlobalData inferred that LN-145 from Cohort 2 demonstrated an ORR of 38% (2 complete responses, 18 partial responses and 1 unconfirmed partial response) in 55 consecutively dosed post-PD-1 subjects and heavily pretreated subjects, with a mean of 3.1 lines of prior therapy including anti-PD1, showed high baseline tumor burden.<br><br>The disease control rate was 76% and at 7.4-month median follow-up, responses were maintained in the majority of subjects (only 4/21 responders had progressed at the time of data analysis).<br><br>http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2398790 **May 31, 2019** Updated Results of Studies in Advanced Cervical Cancer and Melanoma Support Long-Term Efficacy of Iovance Tumor Infiltrating Lymphocyte (TIL) Therapy Based on the results announced by the Iovance Biotherapeutics, Inc., in the press release, GlobalData inferred that ORR of 38% (2 complete responses and 23 partial responses) in 66 consecutively dosed post-PD-1 subjects with Stage IIIC/IV unresectable melanoma. Subjects had experienced a mean of 3.3 lines of prior therapy including anti-PD1 blocking antibody, and had a high baseline tumor burden. The |

disease control rate was 80%. At 8.8-month median follow-up, median duration of response had not been reached (range 1.4+ to 19.8+ months). http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2400232 **June 04, 2019** Iovance Biotherapeutics Inc Corporate Presentation Based on the results presented, GlobalData inferred that 38% ORR was observed.

| **Responses** | **N=66 (%)** |
|---|---|
| Objective Response Rate | 25 (38%) |
| Complete Response | 2 (3%) |
| Partial Response | 23 (35%) |
| Stable Disease | 28 (42%) |
| Progressive Disease | 9 (14%) |
| Non-Evaluable | 4 (6%) |
| Disease Control Rate | 53 (80%) |

phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA3MTc0fENoaWxkSUQ9NDIwMDA3fFR5cGU9MQ==&t=1 **June 01, 2019** Presented at the 55th Annual Meeting of American Society of Clinical Oncology (ASCO 2019), May 31 - June 04, 2019, Chicago, Illinois, USA Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients who progressed on multiple prior therapies including anti-PD-1.
Session: Developmental Immunotherapy and Tumor Immunobiology
Abstract no: 2518 Amod Sarnaik et al. Based on the results presented, GlobalData inferred that 55 subjects were analyzed in the study. Heavily pretreated metastatic melanoma subjects with lifileucel treatment reported in 38% objective response rate (2 CR, 18 PR, 1 uPR) with high baseline disease burden who received prior anti-PD1 and BRAF/MEK inhibitor if BRAF mutated. Of 21 responders four have progressed with median follow up of 7.4 months. Overall disease control was 76%. Improved responses in some subjects were observed with longer follow up. Most (54) subjects progressed on prior anti-PD1 and those with PD-L1 negative status (TPS < 5%) were among responders. http://abstracts.asco.org/239/AbstView_239_266867.html **June 05, 2019**

Presented at the Jefferies 2019 Global Healthcare Conference, June 04-07, 2019, Boston, MA, USA

Based on the results presented, GlobalData inferred that reduction in tumor burden was observed in 81 % subjects during the study. Mean time to response was observed as 1.9 months (1.3-5.6). http://www.wsw.com/webcast/jeff118/iova/?lobby=true&day=2 (Slides

04,12,15,16,17,18,19,20,21,22,36) **November 08, 2019** Iovance Biotherapeutics Announces Updated Phase 2 Clinical Data from the Lifileucel Metastatic Melanoma Trial at the Society for Immunotherapy of Cancer 34th Annual Meeting Based on the results announced in the press release., GlobalData inferred that cohort 2 objective response rate determined by independent review committee (IRC) was 35 %, which aligns well with the investigator assessed ORR of 36 %. Median duration was not reached as assessed by IRC or investigator at 11.3 months follow-up, Median DOR was not reached at a longer study follow-up of 12.8 months as assessed by investigator for 66 subjects in Cohort 2. Overall concordance rate of 89.4 % between investigator assessment and IRC assessment (n=66). https://www.globenewswire.com/news-release/2019/11/08/1943947/0/en/Iovance-Biotherapeutics-Announces-Updated-Phase-2-Clinical-Data-from-the-Lifileucel-Metastatic-Melanoma-Trial-at-the-Society-for-Immunotherapy-of-Cancer-34th-Annual-Meeting.html Based on the results reported, independent review committee was 35 %, which aligns well with the investigator assessed ORR of 36 %. Overall concordance rate of 89.4 % between investigator assessment and IRC assessment (n=66). https://www.globenewswire.com/news-release/2019/11/08/1943947/0/en/Iovance-Biotherapeutics-Announces-Updated-Phase-2-Clinical-Data-from-the-Lifileucel-Metastatic-Melanoma-Trial-at-the-Society-for-Immunotherapy-of-Cancer-34th-Annual-Meeting.html **November 14, 2019** Iovance Biotherapeutics Inc. Corporate Presentation Based on the results presented at SITC 2019, GlobalData inferred that overall concordance rate of investigator and IRC read of response was 89.4%. Median DOR by the investigator and IRC is not reached.

| **Cohort 2,N=66, n (%)** | | |
|---|---|---|
| **Response (RECIST v1.1)** | **ORR by IRC** | **ORR by Investigator** |
| Objective Response Rate (ORR) | 23 (34.8%) | 24 (36.4%) |
| Complete Response (CR) | 2 (3.0%) | 2 (3.0%) |
| Partial Response (PR) | 21 (31.8%) | 22 (33.3%) |
| Stable Disease (SD) | 25 (37.9%) | 29 (43.9%) |

| | | |
|---|---|---|
| Progressive Disease (PD) | 14 (21.2%) | 9 (13.6%) |
| Non-Evaluable | 4 (6.1%) | 4 (6.1%) |
| Disease Control Rate (DCR) | 48 (72.7%) | 53 (80.3%) |
| Median Duration of Response (DOR) | Not Reached | Not Reached |
| Min, Max | 1.6+, 21.2+ | 2.2+, 21.2+ |

http://ir.iovance.com/static-files/1b1e5731-fa4e-4341-8454-eec6e83ff2ce
**November 21, 2019** Iovance Biotherapeutics Announces Results of a Subgroup Analysis of Patients in the Lifileucel Metastatic Melanoma Study who are Primary Refractory to Anti-PD-1/L1 Therapy Based on the results announced by Iovance Biotherapeutics in the press release, GlobalData inferred that in 42 primary refractory subjects enrolled in Cohort 2 of C-144-01 study, defined as having had the best response of progressive disease (PD) on their first anti-PD-1/L1 treatment, an objective response rate (ORR) of 41 percent, as assessed by the investigator, was observed. The median duration of response (DOR) was not reached at 12 months of study follow-up (range: 2.8+ to 21.2+ months) and 71 percent of responders who are primary refractory to anti PD-1/L1 therapy remain on study In the subgroup analysis conducted for primary refractory subjects in Cohort 2 of the C-144-01 study, Tumor infiltrating lymphocyte (TIL) demonstrates excellent efficacy and durability of response. Primary refractory subjects included 42 of the 66 dosed subjects in Cohort 2 who had a best response of progressive disease to the first anti-PD-1/L1. http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-results-subgroup-analysis **November 2019**

Presented at the 2019 Society for Melanoma Research (SMR) Congress, November 20 - 23, 2019, Salt Lake City, Utah, USA Lifileucel (a cryopreserved autologous tumor infiltrating lymphocyte therapy) produces durable responses at one-year median study follow-up in patients with advanced metastatic melanoma previously progressed/ refractory to multiple prior therapies including anti-PD-1 Session: Late Breaking Abstracts Omid Hamid etal., Based on the results reported, GlobalData inferred that a total of 66 subjects were analysed in the cohort 2. There was about 36.4% (2 complete response, 22 partial response) of Overall response rate and 80.3% of Disease Control Rate as per investigator. The median Duration of Response (mDOR) (95% CI [6.4, NR]) was not reached at

12.0 months of median study followup. 63% of responders continue in response. There was an improvement of response overtime in some subjects.

ORR of 40.5% (17/42) was demonstrated in subjects who were primary refractory to checkpoint inhibitors (Best Overall Response of PD to the earliest anti-PD1/L1 treatment). https://registration.sitesolutionsworldwide.com/synergy/v_1_/event_files/Late_Breaking_Abstracts_2019.pdf (Page - 9) **February 2020** Iovance Biotherapeutics Inc. Corporate Presentation Based on the results presented GlobalData inferred that in heavily pretreated subjects (3.3 mean prior therapies) ORR was 36 %, DCR was 80 %, median DOR was not reached, and cohort 2 update at SMR 2019 for n=42 subjects primary refractory to anti PD 1/L1 defined as BOR of PD to the earliest anti PD 1/L1 for which mean duration on first anti PD 1/L1 was 3.1 months and 57% of PD-L1 high/positive (TPS greater than or equal to 1%) TIL therapy provides deep responses i.e nearly all responders are greater than 30 % Median study follow up of 15.5 months as of 2nd jan 2020 Mean TIL cells infused was 27.3 x $10^9$ and median number of IL-2 doses was 5.5 Subjects with PD-L1 negative status TPS<5% were among responders

| Characteristic | Cohort 2, n=42 (%) |
|---|---|
| **Gender (%)** | |
| Male | 26 (62) |
| Female | 16 (38) |
| **Age** | |
| Median | 56 |
| MIn, Max | 20.77 |
| **Prior Therapies, n (%)** | |
| Mean # prior therapies | 3.3 |
| Anti-CTLA-4 | 33 (79) |
| Anti-PD-1 | 42 (100) |
| BRAF/MEK | 9 (21) |
| **Progressive disease (PD) for at least 1 prior therapy** | |
| Anti-CTLA-4 | 29 (88)* |
| Anti-PD-1 | 42 (100) |

| Characteristic | Cohort 2, n=42 (%) |
|---|---|
| **BRAF status, n (%)** | |
| Mutated V600 | 11 (26) |
| Wild Type | 29 (69) |
| Unknown | 2 (5) |
| **Target lesion sum of diameter (mm)** | |
| Mean (SD) | 114 (78) |
| MIn, Max | 17, 343 |

https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f (Slide no: 21, 22, 27) **May 27, 2020** Iovance Reports Pivotal Cohort 4 Data for Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel from C-144-01 Clinical Study

in Advanced Melanoma Based on the initial results announced in the press release, GlobalData inferred that the overall response rate (ORR) was 32.4% in the first 68 subjects in Cohort 4 at 5.3 months of median study follow up, highly consistent with data observed in Cohort 2 with comparable study follow up. The median duration of response was not reached at 18.7 months of study follow up in Cohort 2. Lifileucel shows 1 complete response and 21 partial responses, 2 of which are yet to be confirmed with follow up visits and a disease control rate of 72.1%. The ORR was 33%. The overall response rate was 34.3%, including three complete responses, 43 partial responses (two of which are yet to be confirmed with follow up visits) and a disease control rate of 76.1% in Cohort 2 plus 4 (n=134) and median DOR was not reached at 10.6 months of median study follow up. https://www.globenewswire.com/news-release/2020/05/27/2039716/0/en/Iovance-Reports-Pivotal-Cohort-4-Data-for-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Lifileucel-from-C-144-01-Clinical-Study-in-Advanced-Melanoma.html **August 2020** Iovance Biotherapeutics Inc Corporate Presentation August 2020 Based on the results presented, GlobalData inferred the overall responsive rate of cohort 2 by sub groups

| **Subgroups** | | **n/N** | **ORR** | **95% CI** |
|---|---|---|---|---|
| **Overall** | | 24/66 | 36.4 | 24.9, 49.1 |
| **Baseline Lactate Dehydrogenase** | | 15/39 | 38.5 | 23.4, 55.4 |
| | 1-2xULN | 8/19 | 42.1 | 20.3, 66.5 |
| | >2xULN | 1/8 | 12.5 | 0.3, 52.7 |
| **Baseline target lesion (sum of diameters)** | < 70mm | 14/26 | 53.8 | 33.4, 73.4 |
| | > 70mm | 10/40 | 25.0 | 12.7, 41.2 |
| **Patient with baseline liver lesion** | | 8/23 | 34.8 | 16.4, 57.3 |
| **Patient with baseline brain and/or liver lesion** | | 9/28 | 32.5 | 15.9, 52.4 |
| **Time from stop of anti-PD-1/PD-L1 to til infusion** | < median (4.76 months) | 12/33 | 36.4 | 20.4, 54.9 |
| | > median (4.76 months) | 12/33 | 36.4 | 20.4, 54.9 |

https://ir.iovance.com/static-files/dd026048-1c0a-42ff-bf4d-bec7f9acbd98 (Slide No: 25) **October 8, 2020** Iovance Biotherapeutics Inc. Corporate Presentation Based on the results presented, GlobalData inferred that in cohort 2 n=66 subjects

(3.3 mean prior therapies) ORR was 36%, DCR was 80%, median DOR was not reached.

| **CHARACTERISTIC** | **Cohort 2, N=66, (%)** |
|---|---|
| **Gender** | **n (%)** |
| Female | 27 (41) |
| Male | 39 (59) |
| **Age** | |
| Median | 55 |
| Min, Max | 20, 79 |
| **Prior therapies** | |
| Mean # prior therapies | 3.3 |
| Anti-PD-1 | 66 (100) |
| Anti-CTLA-4 | 53 (80) |
| BRAF/MEK | 15 (23) |
| **Progressive Disease for at least 1 prior therapy** | |
| Anti-PD-1 | 65 (99) |
| Anti-CTLA-4 | 41 (77(1)) |
| **Baseline ECOG score** | |
| 0 | 37 (56) |
| 1 | 29 (44) |
| **CHARACTERISTIC** | **Cohort 2, N=66, (%)** |
| BRAF Status | n (%) |
| Mutated V600 | 17 (26) |
| Wild Type | 45 (68) |
| Unknown | 3 (5) |
| Other | 1 (2) |
| **Target Lesions Sum of Diameter (mm)** | |
| Mean (SD) | 106 (71) |
| Min, Max | 11, 343 |

https://ir.iovance.com/static-files/14662ea1-537d-4967-a558-94ae63ec1154
**January 14, 2021**

Presented at the Virtual 39th Annual J.P. Morgan Healthcare Conference, January 11 - 14, 2021, San Francisco, California, USA

Based on the results presented, GlobalData inferred that median DOR still not reached at 28.1 months of median study follow up.

Melanoma Cohort 2 showed 36.4% ORRby investigator and 34.8% ORR as read

by independent review committee (IRC) (N=66).

Potentially efficacious treatment for subjects with limited options in heavily pretreated metastatic melanoma subjects (3.3 mean prior therapies). ORR 36%, DCR 80%, Mean TIL cells infused: 27.3 x 109.

A 79% of responders had received prior ipilimumab. Best Overall Response was seen and responses deepen over time in cohort 2. 81% (50/62) of subjects had a reduction in tumor burden. Mean Time to response 1.9 months (range 1.3-5.6).

Lifileucel has demonstrated potential efficacy and durability of response for subjects with metastatic melanoma regardless of prior therapy with immune checkpoint therapies, or BRAF status.
https://jpmorgan.metameetings.net/events/healthcare21/sessions/35760-iovance-biotherapeutics-inc/webcast?gpu_only=true&kiosk=true (Slides 05,16,17,18,19,20,21,22) **February 25, 2021** Iovance Biotherapeutics reports fourth quarter and full year 2020 financial results and corporate updates Based on the results announced in the press release, GlobalData inferred that available care for cohort 2 subjects was chemotherapy, with an overall response rate of four to ten percent and overall survival of only seven to eight months.
https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-2 **April 10, 2021**

Presented at the 112th Virtual Annual Meeting of the American Association for Cancer Research (AACR 2021), April 10 - 15, 2021, Washington, D.C., USA

Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic) melanoma: durable duration of response at 28 month follow up
Session: CTPL02 - Immuno-oncology and Cell Therapy Trials
Abstract No.: CT008

Jason Alan Chesney et al., Based on the results presented, GlobalData inferred that ORR by Investigator was 36.4% (3 CR, 21 PR). One patient converted from a PR to CR at 24 mo after lifileucel therapy. Median time to first response was 1.4 mos (range: 1.3-5.6 mos). Median duration of response (mDOR) was still not reached at median follow-up of 28 mos (DOR range: 2.2-35.2 mos). After a median study follow-up of 28.1 months, median DOR was still not reached (range 2.2, 35.2+). Mean number of TIL cells infused: 27.3 x 109. Responses were demonstrated in subjects who received prior anti-CTLA-4 or BRAF/MEK inhibitors. 79% of responders had received prior ipilimumab. One PR converted to CR after 24 months post-lifileucel.

| **RESPONSE** | **PATIENTS, N=66**<br>**n (%)** |
|---|---|

| | | |
|---|---|---|
| Objective Response Rate | 24 | 36.4 |
| Complete Response Partial Response | 21 | 31.8 |
| Stable Disease | 29 | 43.9 |
| Progressive Disease | 9 | 13.6 |
| Non-Evaluable(1) | 4 | 6.1 |
| Disease Control Rate | 53 | 80.3 |
| Median Duration of Response | Not Reached | |
| Min, Max (months) | 2.2, 35.2+ | |

https://www.abstractsonline.com/pp8/#!/9325/presentation/5139
https://www.iovance.com/wp-content/uploads/AACR21_C-144-01_Long-Term-Follow-Up_Chesney_CT008_FINAL_updated_11APR2021.pdf **May 12, 2021** Lifileucel, a Tumor-Infiltrating Lymphocyte Therapy, in Metastatic Melanoma Amod A. Sarnaik et al. Journal of Clinical Oncology, 2021 Based on the results published, GlobalData inferred that 66 subjects were enrolled in this study. The objective response rate was 36% (95% CI, 25 to 49), with two complete responses and 22 partial responses. Disease control rate was 80% (95% CI, 69 to 89). Median duration of response was not reached after 18.7-month median study follow-up (range, 0.2-34.1 months). In the primary refractory to anti–PD-1 or PD-L1 therapy subset, the objective response rate and disease control rate were 41% (95% CI, 26 to 57) and 81% (95% CI, 66 to 91), respectively Efficacy Outcomes by Investigator Assessment:

| Response (RECIST v1.1) (N = 66) | Cohort 2 |
|---|---|
| ORR, No. (%) (95% CI) | 24 (36) (25 to 49) |
| DCR, No. (%) (95% CI) | 53 (80) (69 to 89) |
| Best overall response, No. (%) | |
| CR | 2 (3) |
| PR | 22 (33) |
| SD | 29 (44) |
| PD | 9 (14) |
| Non evaluable | 4 (6) |

https://ascopubs.org/na101/home/literatum/publisher/asco/journals/content/jco/0/jco.ahead-of-print/jco.21.00612/20210511/images/large/jco.21.00612t2.jpeg **June 2021** Presented at the 57th Digital Annual Meeting of American Society of Clinical Oncology (ASCO 2021), June 04 - 08, 2021, Chicago, Illinois, USA Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti-PD-1 therapy Session: Melanoma/Skin Cancers Abstract No.: 9505 James Larkin et al, Based on the results presented, GlobalData inferred that the overall

response rate was 36.4% where three subjects with complete response, one new complete remission developed at 24 months and 21 subjects with partial response. The median duration of response (mDOR) was not reached at median follow-up of 28 mos (DOR range: 2.2- 35.2 months). In responders, the median cumulative duration and median prior lines of anti-PD-1 therapy was 4.4 months (range: 1.4-22.5 mos), and 1.5 (range: 1-4). There was meaningful increase in suration of response to TIL with primary anti-PD-1 resistance and lower duration of time on prior anti-PD-1 therapy. There was one-time lifileucel treatment results in 36.4% ORR, and mDOR was not reached at 28 months of median study follow up. There was one PR converted to new CR at 24 months as response continue to deepen. The DOR was positively associated with primary resistance to prior anti-PD-1 therapy and with shorter cumulative prior duration of anti-PD-1 therapy. The lifileucel showed better clinical outcome when used earlier upon detection of progression on prior anti-PD-1 rather than retreatment with anti-PD-1 based regimens. The **Findings:**

| **Parameter** | **HR (95% CI)** | **P-value** |
|---|---|---|
| Primary refractory to anti-PD-1/PD-L1 | 0.263 (0.075, 0.921) | 0.0367 |
| Duration of prior anti-PD-1/PD-L1 use (≤ median of 5.1 mos vs > median) | 0.218 (0.056, 0.854) | 0.0288 |
| Cumulative duration on prior anti–PD-1 / anti–PD-L1 | | |
| For each 3-month decrease in exposure to prior anti–PD-1 / anti–PD-L1 | 0.715 (0.518, 0.987) | |
| For each 6-month decrease in exposure to prior anti–PD-1 / anti–PD-L1 | 0.511 (0.268, 0.974) | 0.041 |

https://meetinglibrary.asco.org/record/196423/abstract https://www.iovance.com/wp-content/uploads/Iovance_ASCO-2021_C-144-01_Cohort-2_Larkin_Presentation_2021-06-06.pdf https://www.iovance.com/wp-content/uploads/Iovance_ASCO-2021_C-144-01-Cohort-2_long-term-FU-abstract_19May2021.pdf **June 06, 2021** Iovance Biotherapeutics Announces 33-Month Follow Up Data for Lifileucel in Advanced Melanoma at ASCO 2021 Annual Meeting Based on the results presented, GlobalData inferred that the median duration of response (DOR) not reached at 33.1 months in cohort 2 in subjects. The cohort 2 in the C-144-01 clinical study was very exciting and continued to support the durability of responses after lifileucel in treating subjects with melanoma. The median duration of response was still not been reached at 33 months of median study follow up. The shorter duration of prior anti-PD-1 therapy was associated with longer duration of response after lifileucel. The median duration of response was not reached at 33.1 months of median study follow up (range: 2.2 to 38.5+ months) and overall response Rate remained at 36.4%. The responses deepened over time and one subject converted from partial to complete response at 24 months post lifileucel infusion.

| | |
|---|---|
| | https://www.globenewswire.com/news-release/2021/06/06/2242393/0/en/Iovance-Biotherapeutics-Announces-33-Month-Follow-Up-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html **June 06, 2021** ASCO Update Call Based on the results presented, GlobalData inferred that there were 17.7% subjects who had deepening of response; 1 partial response converted to complete response after 24 months post -lifileucel in subjects. https://ir.iovance.com/static-files/7f1edb46-6a77-4e34-b907-6402f4b5355f-(Slide No:12)<br>Based on the results reported, lifileucel showed clinically meaningful and durable objective response rate (ORR) in the rare and difficult-to-treat mucosal melanoma subjects. |
| Safety Result | **December 06, 2023**<br><br>Presented at the European Society for Medical Oncology Immuno-Oncology Annual Congress (ESMO IO 2023), December 06 - 08, 2023, Geneva, Switzerland Long-term Efficacy and Patterns of Response of Lifileucel Tumor-infiltrating Lymphocyte (Til) Cell Therapy in Patients with Advanced Melanoma: A 4-year Analysis of the C-144-01 Study Session: Proffered Paper session 2 Abstract No.: 119O Martin Wermke et al.Based on the results presented, GlobalData inferred that treatment-emergent adverse events were consistent with known safety profiles of lymphodepletion and IL-2.https://cslide.ctimeetingtech.com/immuno23hybrid/attendee/confcal/show/session/10<br><br>**November 16, 2023**<br><br>Iovance Biotherapeutics Announces Clinical Data for Lifileucel in Advanced Mucosal Melanoma at the European Society for Medical Oncology (ESMO) CongressBased on the results announced by Iovance Biotherapeutics Inc., in the press release, GlobalData inferred that treatment emergent adverse events (TEAEs) were consistent with known safety profiles of lymphodepleting chemotherapy and interleukin-2 (IL-2).https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-clinical-data-lifileucel-1<br><br>**November 01, 2023**<br><br>Presented at the 38th Virtual Annual Meeting and Pre-Conference Programs of the Society for Immunotherapy of Cancer (SITC 2023), November 01 - 05, 2023, San Diego, California, USA Long-term Efficacy and Safety of Lifileucel Tumor-infiltrating Lymphocyte (Til) Cell Therapy in Patients with Advanced Melanoma: A 4-year Analysis of the C-144–01 Study Session: Clinical Trial In Progress |

Abstract No.: 776 Theresa Medina et al.Based on the results presented, GlobalData inferred that the treatment-emergent adverse events (AEs) were consistent with known safety profiles of lymphodepletion and IL-2 and their incidence decreased over time. There were no new serious treatment-related adverse events(AEs) were reported after 6 months post-lifileucel infusion.https://jitc.bmj.com/content/11/Suppl_1/A873

**October 20, 2023**

Presented at the European Society for Medical Oncology Congress (ESMO 2023), October 20-24, 2023, Madrid, Spain

Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy in Patients (Pts) with Advanced Mucosal Melanoma after Progression on Immune Checkpoint Inhibitors (ICI): Results from the Phase II C-144-01 Study
Session: Mini Oral session
Abstract No.: 1086MO

Evidio Domingo-Musibay et al.Based on the results presented, GlobalData inferred that treatment-emergent adverse events were consistent with known safety profiles of lymphodepleting chemotherapy and IL-2. The most common (≥30%) Grade 3/4 non-hematologic treatment-emergent adverse events were febrile neutropenia (58%) and hypotension (33%). Grade 3/4 hematologic laboratory abnormalities were consistent with nonmyeloablative lymphodepletion. **Findings:**

| **Preferred Term, n (%)** | **Mucosal Melanoma (N=12)** | |
|---|---|---|
| | **Any grade** | **Grade 3/4** |
| Chills | 9 (75.0) | 0 |
| Febrile neutropenia | 7 (58.3) | 7 (58.3) |
| Diarrhea | 7 (58.3) | 0 |
| Pyrexia | 5 (41.7) | 0 |
| Pruritus | 5 (41.7) | 0 |
| Hypotension | 5 (41.7) | 4 (33.3) |
| Alopecia | 5 (41.7) | 0 |
| Hypokalemia | 4 (33.3) | 0 |
| Hypoxia | 4 (33.3) | 2 (16.7) |

| **Preferred Term, n (%)** | **Mucosal Melanoma (N=12)** |
|---|---|
| Neutropenia | 12 (100) |
| Leukopenia | 12 (100) |

| | |
|---|---|
| Lymphopenia | 12 (100) |
| Thrombocytopenia | 12 (100) |
| Anemia | 8 (66.7) |

https://cslide.ctimeetingtech.com/esmo2023/attendee/confcal/presentation/list?q=1086MO&r=st%7E9

**April 23, 2023**

Presented at the 49th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2023), April 23 - 26, 2023, Paris, France
Efficacy and Safety of Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy in Patients with Advanced Melanoma Enrolled in Consecutive Cohorts of the C-144-01 Study
Session: Cellular Therapies other than CARs
Abstract No.: P223 Larkin J et al.Based on the results presented, GlobalData inferred that the three most common non-hematologic treatment emergent adverse events (TEAEs) were chills (75.0%), pyrexia (51.9%), and febrile neutropenia (41.7%). All subjects experienced cytopenias consistent with nonmyeloablative lymphodepletion (NMA-LD). Overall, TEAEs were consistent with known safety profiles of NMA-LD and IL-2, incidence decreased over time and were similar across IL-2 dose groups.https://ebmt2023.abstractserver.com/program/#/details/presentations/963

**March 25, 2023**

Presented at the 2023 International Conference on Surgical Cancer Care (SSO 2023), March 22 - 25, 2023, Boston, Massachusetts, USA Lifileucel TIL Cell Therapy in Patients with Advanced Melanoma After Progression on Immune Checkpoint Inhibitors (ICI) Andbtargeted Therapy: Tumor Tissue Procurement Data from the C-144-01 Study
Abstract No.: 64 Michael E Egger et al.Based on the results presented, GlobalData inferred that 3% of resected subjects had G3/4 tumor-resection adverse events (AEs) related to surgery, which included cellulitis and postsurgical site-related AEs, and nausea, abdominal pain, and hypoxia. Subjects had no surgery-related AEs that prevented TIL infusion. Treatment-emergent AEs were consistent with prior reports.https://link.springer.com/content/pdf/10.1245/s10434-023-13332-7.pdf?pdf=inline%20link

**December 08, 2022**

Presented at the European Society for Medical Oncology Immuno-Oncology Annual Congress (ESMO IO 2022), December 07 - 09, 2022, Geneva,

Switzerland Number of IL-2 doses and clinical outcomes of tumor-infiltrating lymphocyte (TIL) cell therapy: Post hoc analysis of the C-144-01 trial of lifileucel in patients with advanced melanoma
Session: Mini Oral session 1
Abstract No.: 35MO Jessica Hassel et al.Based on the results presented, GlobalData inferred that all subjects developed G3/4 lymphopenia (per lab values) after NMA-LD (Day 0–4).https://oncologypro.esmo.org/meeting-resources/esmo-immuno-oncology-congress/number-of-il-2-doses-and-clinical-outcomes-of-tumor-infiltrating-lymphocyte-til-cell-therapy-post-hoc-analysis-of-the-c-144-01-trial-of-lifileuc

**November 10, 2022**

Iovance Biotherapeutics Inc., "Investor Event & KOL Roundtable Presentation (Slide No: 08-19)", Nov 2022Based on the results reported, GlobalData inferred that lifileucel is safe. Median number of IL-2 doses administered was 6. All subjects experienced ≥1 TEAE (any grade) in which 94.9% experienced ≥1 Grade 3/4 TEAE. TEAEs were consistent with known safety profiles of NMA-LD and IL-2 and in line with previous reports. Incidence of TEAEs decreased rapidly within the first 2 weeks after lifileucel infusion. Non-Hematologic TEAEs in ≥ 30% of Subjects:

| **Preferred Term, n (%)** | **Any Grade** | **Grade 3/4** |
|---|---|---|
| Chills | 117 (75.0) | 8 (5.1) |
| Pyrexia | 81 (51.9) | 17 (10.9) |
| Febrile neutropenia | 65 (41.7) | 65 (41.7) |
| Hypophosphatemia | 58 (37.2) | 41 (26.3) |
| Hypotension | 52 (33.3) | 17 (10.9) |
| Fatigue | 51 (32.7) | 6 (3.8) |
| Diarrhea | 48 (30.8) | 2 (1.3) |

Grade 3/4 Hematologic Lab Abnormalities:

| **Preferred Term, n (%)** | **Grade 3/4** |
|---|---|
| Leukopenia | 156 (100.0) |
| Lymphopenia | 156 (100.0) |
| Neutropenia | 156 (100.0) |
| Thrombocytopenia | 147 (94.2) |
| Anemia | 111 (71.2) |

https://ir.iovance.com/static-files/b668e3af-7748-41d2-9b58-29108038a59c

**November 08, 2022**

Presented at the hybrid 37th Annual Meeting Pre-Conference Programs of the Society for Immunotherapy of Cancer's (SITC 2022), November 8 – 12, 2022, Boston, Massachusetts, United states Lifileucel TIL cell monotherapy in patients with advanced melanoma after progression on immune checkpoint inhibitors (ICI) and targeted therapy: pooled analysis of consecutive cohorts (C-144–01 study)
Session: Clinical Trials In Progress
Abstract No.: 789 Amod Sarnaik et al.Based on the results presented, GlobalData inferred that the most common (≥30%) grade 3/4 treatment emergent adverse events were thrombocytopenia (77%), anemia (50%), and febrile neutropenia (42%). Treatment emergent adverse events were consistent with known safety profiles of NMA-LD and IL-2, and their incidence decreased within the first 2 weeks post-lifeucel infusion, characteristic of one-time treatment. **Findings:**

| **Preferred Term, n (%)** | **Any Grade** | **Grade 3/4** |
|---|---|---|
| Chills | 117 (75.0) | 8 (5.1) |
| Pyrexia | 81 (51.9) | 17 (10.9) |
| Febrile neutropenia | 65 (41.7) | 65 (41.7) |
| Hypophosphatemia | 58 (37.2) | 41 (26.3) |
| Hypotension | 52 (33.3) | 17 (10.9) |
| Fatigue | 51 (32.7) | 6 (3.8) |
| Diarrhea | 48 (30.8) | 2 (1.3) |
| **Preferred Term, n (%)** | **Grade 3/4** | |
| Leukopenia | 156 | -100 |
| Lymphopenia | 156 | -100 |
| Neutropenia | 156 | -100 |
| Thrombocytopenia | 147 | -94.2 |
| Anemia | 111 | -71.2 |

https://www.iovance.com/uploads/Sarnaik_SITC2022_24-oral-presentation_FINAL-compressed-2426-publication.pdfhttps://jitc.bmj.com/content/10/Suppl_2/A821

**September 10, 2022**

Presented at the Virtual European Society for Medical Oncology Congress (ESMO 2022), September 09 - 13, 2022, Paris, France Efficacy and Safety of Lifileucel, an Investigational Autologous Tumor-infiltrating Lymphocyte (TIL) Cell Therapy, in Patients with Advanced Melanoma Previously Treated with Anti-LAG3 Antibody
Session: Poster session 3

Abstract No.: 844P J J. Larkin et al.Based on the results presented, GlobalData inferred that the incidence of AEs decreased rapidly within 2 weeks of lifileucel infusion. Treatment emergent adverse events (TEAEs) were manageable and expected. No Grade 5 TEAEs were reported. Most common (≥30%) grade 3/4 treatment-emergent adverse events were anemia (85%), thrombocytopenia (85%), febrile neutropenia (39%), leukopenia (31%), neutropenia (31%), and lymphopenia (31%).

| **Preferred Term, n (%)** | **Any Grade** | **Grade 3/4** |
|---|---|---|
| Any TEAE | 13 (100) | 12 (92.3) |
| Anemia | 11 (84.6) | 11 (84.6) |
| Thrombocytopenia | 11 (84.6) | 11 (84.6) |
| Febrile neutropenia | 5 (38.5) | 5 (38.5) |
| Leukopenia | 7 (53.8) | 4 (30.8) |
| Lymphopenia | 6 (46.2) | 4 (30.8) |
| Neutropenia | 6 (46.2) | 4 (30.8) |

https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdfhttps://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano

**May 26, 2022**

Ovance Biotherapeutics Announces Positive Clinical Data for Lifileucel in Advanced MelanomaBased on the results announced by Lovance Biotherapeutics Inc in the press release, GlobalData inferred that the treatment-emergent adverse event profile in both cohorts was consistent with the underlying disease and known adverse event profiles of non-myeloablative lymphodepletion and interleukin-2 (IL-2) and was also consistent between Cohorts 2 and 4.https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data

**May 29, 2020** Iovance Presents Updated Clinical Data for Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel in Advanced Melanoma at ASCO Scientific Program Based on the results announced by Iovance Biotherapeutics Inc, in the press release, GlobalData inferred that the adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens. https://ir.iovance.com/news-releases/news-release-details/iovance-

presents-updated-clinical-data-tumor-infiltrating **May 20, 2020** Long-term follow up of lifileucel (LN-144) cryopreserved autologous tumor infiltrating lymphocyte therapy in patients with advanced melanoma progressed on multiple prior therapies Amod Sarnaik et al Journal of Clinical Oncology, Volume 38, Issue 15, Pages 10006-10006, 2020 Based on the results reported, GlobalData inferred that the adverse event profile was consistent with the underlying advanced disease and the lymphodepletion and IL-2 regimens.
https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.15_suppl.10006 **June 2017**

Presented at the 53rd American Society of Clinical Oncology Annual Meeting (ASCO 2017), June 02-06, 2017, Chicago, Illinois, USA

Efficacy of single administration of tumor-infiltrating lymphocytes (TIL) in heavily pretreated patients with metastatic melanoma following checkpoint therapy
Category: Developmental Therapeutics—Immunotherapy
Abstract No.: 3045

Amod Sarnaik et al.

Based on the preliminary results presented, GlobalData inferred that the most frequent (≥3 patients) non-hematologic grade 3-4 treatment emergent adverse events was hypophosphatemia. Neurotoxicity of grade ≥ 3 was not reported. Deaths or discontinuations due to serious adverse events related to study treatment were not observed.
http://abstracts.asco.org/199/AbstView_199_185466.html **June 06, 2017**

Presented at the Jefferies 2017 Global Healthcare Conference, June 06-09, 2017, New York, USA

Based on the results presented, GlobalData inferred that treatment emergent adverse events were reported during the study.

| Event | Any grade n(%) | Grade ≥ 3 n(%) | Grade 5 n(%) |
|---|---|---|---|
| Number of subject reporting at least 1 treatment emergent serious adverse event | 9 (56.3) | 9 (56.3) | 1 (6.3) |
| Febrile Neutropenia | 4 (25.0) | 4 (25.0) | 4 (25.0) |
| Pyrexia | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Systemic inflammatory response syndrome | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Parvovirus B19 infection | 1 (6.3) | 1 (6.3) | 1 (6.3) |
| Viral infection | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Neutropil count decreased | 3 (18.8) | 3 (18.8) | 0(0.0) |

| | | | |
|---|---|---|---|
| Platlet count decreased | 3 (18.8) | 2 (12.5) | 0(0.0) |
| Blood bilirubin decreased | 1 (6.3) | 1 (6.3) | 0(0.0) |
| White blood cell count decreased | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Dehydration | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Myelodysplastic syndrome | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Confusional state | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Hypoxia | 1 (6.3) | 1 (6.3) | 0(0.0) |
| Hypotension | 1 (6.3) | 1 (6.3) | 0(0.0) |

http://wsw.com/webcast/jeff105/lbio/?lobby=true&day=1 (Slides 12,17,18,19,20,21,22,23,24,25,37) **December 2017** Presented at 2018 ASCO Gastrointestinal (GI) Cancers Symposium (ASCO GI 2018), January 18 - 20, 2018, San francisco, CA, USA Novel cryopreserved tumor infiltrating lymphocytes (LN-144) administered to patients with metastatic melanoma demonstrates efficacy and tolerability in a multicenter Phase 2 clinical trial Session: Late-Breaking Abstracts - Poster presentations - Cellular Therapy Approaches
Abstract No.: P515 Amod Sarnaik et al.

Based on the results presented, GlobalData inferred that the a comparable tolerability of cryopreserved LN-144 was reported. The safety profile reported for cohort 1 subjects receiving the non-cryopreserved LN-144 continued to for this late stage subjects population. The most common treatment-emergent adverse events reported in both cohorts by frequency were anaemia, nausea, neutrophil count decreased, febrile neutropenia, platelet count decreased.
https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-017-0297-3?site=jitc.biomedcentral.com **September 06, 2018** Presented at the Rodman & Renshaw 20th Annual Global Investment Conference, September 04-06, 2018, New York City, New York, USA Based on the results presented, GlobalData inferred that the treatment-emergent adverse events reported were ≥ 30%.
http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk5NjIyfENoaWxkSUQ9NDExMTMwfFR5cGU9MQ==&t=1 **December 13, 2017** Iovance Biotherapeutics Inc Investor and Analyst Day Presentation Based on the results presented, GlobalData inferred that treatment emergent adverse events were reported during the study.

| **PREFERRED TERM** | | **Cohort 2 (N= 17)** | |
|---|---|---|---|
| | **Any Grade** | **Grade 3/4** | **Grade 5** |
| | n (%) | n (%) | n (%) |
| Number of patients reporting at least oneTreatment-Emergent AE | 16 (94.1) | 16 (94.1) | 0 |
| Pyrexia | 13 | 1 (5.9) | 0 |

| | | | |
|---|---|---|---|
| | (76.5) | | |
| Anaemia | 11 (64.7) | 10 (58.8) | 0 |
| Neutrophil count decreased | 10 (58.8) | 10 (58.8) | 0 |
| Platelet count decreased | 10 (58.8) | 8 (47. 1) | 0 |
| Febrile neutropenia | 10 (58.8) | 8 (47.1) | 0 |
| Fatigue | 10 (58.8) | 0 | 0 |
| Chills | 9 (52.9) | 1 (5.9) | 0 |
| Nausea | 9 (52.9) | 0 | 0 |
| White blood cell count decreased | 8 (47.1) | 8 (47.1) | 0 |
| Lymphocyte count decreased | 6 (35.3) | 6 (35.3) | 0 |
| Diarrhoea | 6 (35.3) | 0 | 0 |
| Decreased appetite | 6 (35.3) | 0 | 0 |

https://edge.media-server.com/m6/p/fhqnhyoj

**November 2018**

Presented at the 33rd Annual Meeting and Pre-Conference Programs of the Society for Immunotherapy of Cancer (SITC 2018), November 07 - 11, 2018, Washington, D.C, USA

Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients following progression on checkpoint inhibitors
Session: Clinical Trials (In Progress)
Abstract No.: O22

Amod Sarnaik et al. Based on the preliminary results presented, GlobalData inferred that as per investigator assessment, none of the grade 5 serious adverse events were due to any of study treatment.
https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-018-0423-x (Pages 385-386) **November 06, 2018** Iovance Biotherapeutics Announces Updated Phase 2 Clinical Data from the Lifileucel Metastatic Melanoma Trial at the Society for Immunotherapy of Cancer's 33rd Annual Meeting Based on the results announced by Iovance Biotherapeutics Inc., in a press release, GlobalData inferred that most common treatment emergent adverse events were observed in this cohort include chills, febrile neutropenia, anaemia, decreased platelet count, pyrexia, and hypophosphataemia. Two grade 5 events were occurred, one was deemed not related to the lifileucel by investigator and other possibly related.

http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2375545 **November 09, 2018** Iovance Biotherapeutics Inc Clinical Program Update Presentation Based on the results presented, GlobalData inferred that Lifileucel was well tolerated.

| **PREFERRED TERM** | | **Cohort 2 (N=47)** | |
|---|---|---|---|
| | **Any Grade, n (%)** | **Grade 3/4, n (%)** | **Grade 5, n (%)** |
| Number of patients reporting at least one Treatment-Emergent AE | 47(100) | 45 (95.7) | 2 (4.3) |
| Thrombocytopenia | 42 (89.4) | 38 (80.9) | 0 |
| Chills | 36 (76.6) | 3 ( 6.4) | 0 |
| Neutropenia | 29 (61.7) | 25 (53.2) | 0 |
| Febrile neutropenia | 28 (59.6) | 25 (53.2) | 0 |
| Anemia | 27 (57.4) | 22 (46.8) | 0 |
| Pyrexia | 25 (53.2) | 7 (14.9) | 0 |
| Hypophosphatemia | 23 (48.9) | 17 (36.2) | 0 |
| Leukopenia | 21 (44.7) | 20 (42.6) | 0 |
| Fatigue | 17 (36.2) | 0 | 0 |
| Hypotension | 17 (36.2) | 4 ( 8.5) | 0 |
| Lymphopenia | 17 (36.2) | 17 (36.2) | 0 |
| Tachycardia | 15 (31.9) | 1 ( 2.1) | 0 |

phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAxNzc0fENoaWxkSUQ9NDEzNTM2fFR5cGU9MQ==&t=1 **March 1, 2019** Presented at the 2019 ASCO-SITC Clinical Immuno-Oncology Symposium (ASCO SITC 2019), February 28 - March 2, 2019, San Francisco, California, USA Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients previously treated with at least one prior systemic therapy
Session: Poster Session B
Abstract No.: 136 Amod Sarnaik et al, Based on the preliminary results presented, GlobalData inferred that decreased frequency of adverse events over time was observed in subjects. LN-144 was well tolerated in subjects with metastatic melanoma. https://meetinglibrary.asco.org/record/170363/abstract
**May 15, 2019**

Iovance Biotherapeutics Announces Updates to Tumor Infiltrating Lymphocyte

(TIL) Therapy Clinical Programs

Based on the results announced by the Iovance Biotherapeutics, Inc., in the press release, GlobalData inferred that LN-145 resolved adverse events to baseline 2 weeks post TIL infusion in cohort 2.

http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2398790 **June 04, 2019** Iovance Biotherapeutics Inc Corporate Presentation Based on the results presented, GlobalData inferred that following adverse events observed.

| **PREFERRED TERM** | **Cohort 2, N=66** | | |
|---|---|---|---|
| | **Any Grade n (%)** | **Grade 3/4 n (%)** | **Grade 5 n (%)** |
| Number of patients reporting at least one Treatment-Emergent AE- | 65 (98.3) | 63 (95.3) | 2 (3.0) |
| Thrombocytopenia | 59 (89.4) | 53 (80.3) | 0 |
| Chills | 52 (78.8) | 4 ( 6.1) | 0 |
| Anemia | 44 (66.7) | 36 (54.5) | 0 |
| Pyrexia | 39 (59.1) | 11 (16.7) | 0 |
| Febrile neutropenia | 36 (54.5) | 35 (53.0) | 0 |
| Neutropenia | 36 (54.5) | 25 (37.9) | 0 |
| Hypophosphatemia | 29 (43.9) | 22 (33.3) | 0 |
| Fatigue | 27 (40.9) | 1 (1.5) | 0 |
| Leukopenia | 27 (40.9) | 22 (33.3) | 0 |
| Hypotension | 23 (34.8) | 7 (10.6) | 0 |
| Tachycardia | 22 (33.3) | 1 ( 1.5) | 0 |
| Lymphopenia | 21 (31.8) | 19 (28.8) | 0 |

phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA3MTc0fENoaWxkSUQ9NDIwMDA3fFR5cGU9MQ==&t=1 **June 01, 2019** Presented at the 55th Annual Meeting of American Society of Clinical Oncology (ASCO 2019), May 31 - June 04, 2019, Chicago, Illinois, USA Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients who progressed on multiple prior therapies including anti-PD-1.
Session: Developmental Immunotherapy and Tumor Immunobiology
Abstract no: 2518 Amod Sarnaik et al. Based on the results presented, GlobalData inferred that adverse events resolved to baseline, 2 weeks post TIL infusion, a potentially important benefit of one-time TIL therapy.

http://abstracts.asco.org/239/AbstView_239_266867.html **November 2019**

Presented at the 2019 Society for Melanoma Research (SMR) Congress, November 20 - 23, 2019, Salt Lake City, Utah, USA Lifileucel (a cryopreserved autologous tumor infiltrating lymphocyte therapy) produces durable responses at one-year median study follow-up in patients with advanced metastatic melanoma previously progressed/ refractory to multiple prior therapies including anti-PD-1 Session: Late Breaking Abstracts Omid Hamid etal., Based on the results reported, GlobalData inferred that there were consistent adverse events. https://registration.sitesolutionsworldwide.com/synergy/v_1_/event_files/Late_Breaking_Abstracts_2019.pdf (Page - 09) **February 2020** Iovance Biotherapeutics Inc Corporate Presentation Based on the results presented, GlobalData inferred that treatment emergent adverse events greater than or equal to 30 %.

| **PREFERRED TERM** | | **Cohort 2 (N=42)** | |
|---|---|---|---|
| | **Any Grade, n (%)** | **Grade 3/4, n (%)** | **Grade 5, n (%)** |
| Number of patients reporting at least one Treatment-Emergent AE | 42(100) | 41 (97.6) | 2 (4.8) |
| Thrombocytopenia | 38 (90.5) | 33 (78.6) | 0 |
| Chills | 32 (76.2) | 3 (7.1) | 0 |
| Neutropenia | 21 (50.0) | 15 (35.7) | 0 |
| Febrile neutropenia | 23 (54.8) | 23 (54.8) | 0 |
| Anemia | 30 (71.4) | 25 (59.5) | 0 |
| Pyrexia | 25 (59.5) | 7 (16.7) | 0 |
| Hypophosphatemia | 19 (45.2) | 12 (28.6) | 0 |
| Leukopenia | 18 (42.9) | 15 (35.7) | 0 |
| Fatigue | 18 (42.9) | 1 (2.4) | 0 |
| Hypotension | 14 (33.3) | 5 (11.9) | 0 |
| Lymphopenia | 15 (35.7) | 13 (31.0) | 0 |
| Tachycardia | 13 (31.0) | 1 ( 2.4) | 0 |
| Hypocalcemia | 14 (33.3) | 3 (7.1) | 0 |
| | | | |

| | | | |
|---|---|---|---|
| aminotransferase increased | | | |
| Diarrhea | 13 (31.0) | 1 ( 2.4) | 0 |

https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f (Slide no: 28) **March 2020** Iovance Biotherapeutics Inc Corporate Presentation Based on the results presented, GlobalData inferred that treatment emergent adverse events greater than or equal to 30%.

| **PREFERRED TERM** | | **Cohort 2 (N=42)** | |
|---|---|---|---|
| | **Any Grade, n (%)** | **Grade 3/4, n (%)** | **Grade 5, n (%)** |
| Number of patients reporting at least one Treatment-Emergent AE | 65(98.5) | 63(95.5) | 2(3.0) |
| Thrombocytopenia | 59(89.5) | 53(80.3) | 0 |
| Chills | 52(78.8) | 4(6.1) | 0 |
| Neutropenia | 36(54.5) | 25(37.9) | 0 |
| Febrile neutropenia | 36(54.5) | 35(53.0) | 0 |
| Anemia | 44(66.7) | 36(54.5) | 0 |
| Pyrexia | 39(59.1) | 11(16.7) | 0 |
| Hypophosphatemia | 29(43.9) | 22(33.3) | 0 |
| Leukopenia | 27(40.9) | 22(33.3) | 0 |
| Fatigue | 27(40.9) | 1(1.5) | 0 |
| Hypotension | 23(34.8) | 7(10.6) | 0 |
| Lymphopenia | 27(40.9) | 19(28.8) | 0 |
| Tachycardia | 22(33.3) | 1(1.5) | 0 |
| Hypocalcemia | - | - | 0 |
| Aspartate aminotransferase increased | - | - | 0 |
| Diarrhea | - | - | 0 |

https://ir.iovance.com/static-files/29193916-3d6b-413b-b450-698af14a0a58 **May 27, 2020** Iovance Reports Pivotal Cohort 4 Data for Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel from C-144-01 Clinical Study in Advanced Melanoma Based on the initial results announced in the press release, GlobalData inferred that the adverse event profile was consistent with Cohort 2 and with the underlying advanced disease, lymphodepletion and IL-2 regimens. https://www.globenewswire.com/news-

release/2020/05/27/2039716/0/en/Iovance-Reports-Pivotal-Cohort-4-Data-for-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Lifileucel-from-C-144-01-Clinical-Study-in-Advanced-Melanoma.html **June 2020** Iovance Biotherapeutics Inc Corporate Presentation Based on the results presented, GlobalData inferred that treatment emergent adverse events were greater than or equal to 30%.

| **PREFERRED TERM** | **Cohort 2, N=66** | | |
|---|---|---|---|
| | **Any Grade n (%)** | **Grade 3/4 n (%)** | **Grade 5 n (%)** |
| Number of patients reporting at least one Treatment-Emergent AE- | 66 (100) | 64 (97.0) | 2 (3.0) |
| Thrombocytopenia | 59 (89.4) | 54 (81.8) | 0 |
| Chills | 53(80.3) | 4 ( 6.1) | 0 |
| Anemia | 45 (68.2) | 37 (56.1) | 0 |
| Pyrexia | 39 (59.1) | 11 (16.7) | 0 |
| Febrile neutropenia | 36 (54.5) | 36 (54.5) | 0 |
| Neutropenia | 37 (56.1) | 26 (39.4) | 0 |
| Hypophosphatemia | 30 (45.5) | 23 (34.8) | 0 |
| Fatigue | 26 (39.4) | 1 (1.5) | 0 |
| Leukopenia | 28 (42.4) | 23 (34.8) | 0 |
| Hypotension | 24 (36.4) | 7 (10.6) | 0 |
| Tachycardia | 23 (34.8) | 21 ( 31.8) | 0 |
| Lymphopenia | 23 (34.8) | 1 (1.5) | 0 |

https://ir.iovance.com/static-files/bb47a08e-7d8f-44e4-9b81-a5173a564984 **January 14, 2021**

Presented at the Virtual 39th Annual J.P. Morgan Healthcare Conference, January 11 - 14, 2021, San Francisco, California, USA

Based on the results presented, GlobalData inferred that adverse events tend to be expected, early and transient. Adverse event profile consistent with underlying advanced disease and safety profile of lymphodepletion and IL-2 regimens. Median number of 6 IL-2 doses administered, decreasing frequency of AEs over time reflective of potential benefit of one-time treatment with lifileucel. https://jpmorgan.metameetings.net/events/healthcare21/sessions/35760-iovance-biotherapeutics-inc/webcast?gpu_only=true&kiosk=true (Slides 05,16,17,18,19,20,21,22) **April 10, 2021**

Presented at the 112th Virtual Annual Meeting of the American Association for Cancer Research (AACR 2021), April 10 - 15, 2021, Washington, D.C., USA

Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic) melanoma: durable duration of response at 28 month follow up
Session: CTPL02 - Immuno-oncology and Cell Therapy Trials
Abstract No.: CT008

Jason Alan Chesney et al., Based on the results presented, GlobalData inferred that no new safety risks have been identified for lifileucel during the long-term follow-up. The adverse event profile was consistent with the underlying advanced disease and the safety profile of the NMA-LD and IL-2 regimens. Decreasing frequency of AEs over time is reflective of potential benefit of one-time treatment with lifileucel.

| PREFERRED TERM | Any Grade, n (%) | Grade 3/4, n (%) | Grade 5 |
|---|---|---|---|
| Number of patients reporting at least one Treatment-Emergent AE | 66 (100) | 64 | 2(3.0) |
| Thrombocytopenia | 59 (89.4) | 54 | 0 |
| Chills | 53 (80.3) | 4 | 0 |
| Anemia | 45 (68.2) | 37 | 0 |
| Pyrexia | 39 (59.1) | 11 | 0 |
| Neutropenia | 37 (56.1) | 26 | 0 |
| Febrile neutropenia | 36 (54.5) | 36 | 0 |
| Hypophosphatemia | 30 (45.5) | 23 | 0 |
| Leukopenia | 28 (42.4) | 23 | 0 |
| Fatigue | 26 (39.4) | 1 | 0 |
| Hypotension | 24 (36.4) | 7 | 0 |
| Lymphopenia | 23 (34.8) | 21 | 0 |
| Tachycardia | 23 (34.8) | 1 | 0 |

https://www.abstractsonline.com/pp8/#!/9325/presentation/5139
https://www.iovance.com/wp-content/uploads/AACR21_C-144-01_Long-Term-Follow-Up_Chesney_CT008_FINAL_updated_11APR2021.pdf **May 12, 2021**
Lifileucel, a Tumor-Infiltrating Lymphocyte Therapy, in Metastatic Melanoma
Amod A. Sarnaik et al. Journal of Clinical Oncology, 2021 Based on the results published, GlobalData inferred that safety profile was consistent with known adverse events associated with nonmyeloablative lymphodepletion and interleukin-2. All subjects experienced at least one TEAE, with the most common (≥ 30%) grade 3 or 4 TEAEs being thrombocytopenia (82%), anemia (56%), febrile neutropenia (55%), neutropenia (39%), hypophosphatemia (35%), leukopenia (35%), and lymphopenia (32%), consistent with the toxicity profile of

NMA-LD and IL-2. Fatal TEAEs occurred in two subjects—1 death was because of intra-abdominal tumor hemorrhage reported as possibly related to TIL, and one was because of acute respiratory failure assessed as not related to TIL by the investigator. The incidence of TEAEs, including grade 3 or 4 TEAEs, decreased rapidly over time with no lifileucel-related SAEs reported after 6 months, and no recurrence of irAEs related to prior ICI. TEAEs Occurring in ≥ 20% of subjects:

| Preferred Term, No. (%) | | | Cohort 2 (N = 66) | | | |
|---|---|---|---|---|---|---|
| | Any Grade | | Grade 3 or 4 | | Grade 5 | |
| No. of patients reporting at least one TEAE | 66 | (100) | 64 | (97) | 2 | (3)a |
| Thrombocytopenia | 59 | (89) | 54 | (82) | | 0 |
| Chills | 53 | (80) | 4 | (6) | | |
| Anemia | 45 | (68) | 37 | (56) | | |
| Pyrexia | 39 | (59) | 11 | (17) | | |
| Neutropenia` | 37 | (56) | 26 | (39) | | |
| Febrile neutropenia | 36 | (55) | 36 | (55) | | 0 |
| Hypophosphatemia | 30 | (46) | 23 | (35) | | 0 |
| Leukopenie | 28 | (42) | 23 | (35) | | 0 |
| Fatigue | 26 | (39) | 1 | (2) | | 0 |
| Hypotension | 24 | (36) | 7 | (11) | | 0 |
| Lymphopenie | 23 | (35) | 21 | (32) | | |
| Tachycardia | 23 | (35) | 1 | (2) | | |
| Alopecia | 19 | (29) | | 0 | | 0 |
| Increased AST | 19 | (29) | | 0 | | 0 |
| Decreased appetite | 19 | (29) | 1 | (2) | | 0 |
| Diarrhea | 19 | (29) | 1 | (2) | | 0 |
| Flypokalemia | 17 | (26) | 2 | (3) | | 0 |
| Hypoxia | 17 | (26) | 10 | (15) | | 0 |
| Peripheral edema | 17 | (26) | 1 | (2) | | C |
| Rash | 17 | (26) | 3 | (5) | | 0 |
| Hypocalcemia | 16 | (24) | 3 | (5) | | 0 |
| Hypomagnesemia | 16 | (24) | | 0 | | 0 |
| Increased weight | 16 | (24) | 1 | (2) | | 0 |
| Increased ALT | 15 | (23) | 2 | (3) | | 0 |
| Nausea | 15 | (23) | | 0 | | 0 |
| Increased blood alkaline | 14 | (21) | 2 | (3) | | 0 |

| | |
|---|---|
| | <table><tr><td>phosphatase</td><td></td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Dyspnea</td><td>14</td><td>(21)</td><td>3</td><td>(5)</td><td></td><td>0</td></tr><tr><td>Hypoalbuminemia</td><td>14</td><td>(21)</td><td>3</td><td>(5)</td><td></td><td>0</td></tr><tr><td>Maculopapular rash</td><td>14</td><td>(21)</td><td>6</td><td>(9)</td><td></td><td>0</td></tr><tr><td>Vomiting</td><td>14</td><td>(21)</td><td></td><td>0</td><td></td><td>0</td></tr><tr><td>constipation</td><td>13</td><td>(20)</td><td></td><td>0</td><td></td><td>0</td></tr><tr><td>priritus</td><td>13</td><td>(20)</td><td></td><td>0</td><td></td><td>0</td></tr></table><br><br>https://ascopubs.org/na101/home/literatum/publisher/asco/journals/content/jco/0/jco.ahead-of-print/jco.21.00612/20210511/images/large/jco.21.00612t2.jpeg **June 2021** Presented at the 57th Digital Annual Meeting of American Society of Clinical Oncology (ASCO 2021), June 04 - 08, 2021, Chicago, Illinois, USA Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti-PD-1 therapy Session: Melanoma/Skin Cancers Abstract No.: 9505 James Larkin et al, Based on the results published, GlobalData inferred that there were no new safety risks have been identified for lifileucel during long-term follow-up. https://meetinglibrary.asco.org/record/196423/abstract https://www.iovance.com/wp-content/uploads/Iovance_ASCO-2021_C-144-01_Cohort-2_Larkin_Presentation_2021-06-06.pdf https://www.iovance.com/wp-content/uploads/Iovance_ASCO-2021_C-144-01-Cohort-2_long-term-FU-abstract_19May2021.pdf **June 06, 2021** Iovance Biotherapeutics Announces 33-Month Follow Up Data for Lifileucel in Advanced Melanoma at ASCO 2021 Annual Meeting Based on the results presented, GlobalData inferred that the adverse event profile was consistent with the underlying advanced disease, lymphodepletion and IL-2 regimens, with no new safety risks identified for lifileucel during long-term follow-up. https://www.globenewswire.com/news-release/2021/06/06/2242 |
| Pharmacokinetic Evaluation | |

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|---|---|
| Statistical Method (if any) | **November 08, 2022**<br><br>Presented at the hybrid 37th Annual Meeting Pre-Conference Programs of the Society for Immunotherapy of Cancer's (SITC 2022), November 8 – 12, 2022, Boston, Massachusetts, United states Lifileucel TIL cell monotherapy in patients with advanced melanoma after progression on immune checkpoint inhibitors (ICI) and targeted therapy: pooled analysis of consecutive cohorts (C-144–01 study)<br>Session: Clinical Trials In Progress<br>Abstract No.: 789 Amod Sarnaik et al.Based on the results presented, GlobalData inferred that multivariate analysis was used in this study.https://jitc.bmj.com/content/10/Suppl_2/A821<br><br>**June 06, 2022**<br><br>Presented at the 58th Annual Meeting of American Society of Clinical Oncology (ASCO 2022), June 03 - 07, 2022, Chicago, Illinois, USA Tumor Mutational Burden (TMB) in Immune Checkpoint Inhibitor (ICI)-naïve and -experienced Patients with Metastatic Melanoma Treated with Lifileucel, a Tumor-infiltrating Lymphocyte (TIL) Cell Therapy<br>Session: Melanoma/Skin Cancers<br>Abstract No.: 9524 Harriet M Kluger et al. Based on the pooled results of NCT03645928 and NCT02360579 presented, GlobalData inferred that logistic regression analysis was used in the study.https://meetings.asco.org/abstracts-presentations/210188 |
| Conclusion | The trial was completed. Based on the results reported, GlobalData concluded that lifileucel is safe with clinically meaningful and durable objective response rate (ORR) in subjects with advanced melanoma. |

| Enrollment Data | |
|---|---|
| Trial Start Date (Actual): | 14 Sep 2015 |
| No. of Subjects Planned: | 164 |
| Trial Enrollment Completion Date (Actual): | 01 Dec 2019 |
| No. of Subjects Enrolled: | 181 |
| Enrollment Period (in Months) (Actual): | 51.30 |
| Enrollment Efficiency (%): | 181 |
| Trial End Date (Actual): | 26 May 2022 |
| No. of Sites: | 66 |
| Treatment Period (in Months) (Actual): | 30.23 |
| Trial Duration (in Months) (Actual): | 81.53 |

| Enrollment Rate Parameters: | |
|---|---|
| Subjects/Site: | 2.74 |
| Subjects/Month: | 3.53 |
| Subjects/Site/Month: | 0.05 |

| Trial Cost Overview | |
|---|---|
| **Trial Cost Parameters** | **Cost ($ Millions)** |
| Trial Cost | 31.58 |
| Trial Cost/Month | 0.39 |
| Trial Cost/Site | 0.48 |
| Trial Cost/Subject | 0.17 |

| Trial Cost By Year | |
|---|---|
| **Year** | **Trial Cost ($ Millions)** |
| 2015 | 1.35 |
| 2016 | 4.46 |
| 2017 | 4.46 |
| 2018 | 4.46 |
| 2019 | 4.46 |
| 2020 | 4.46 |
| 2021 | 4.46 |
| 2022 | 1.79 |

| Trial Cost By Components | |
|---|---|
| **Cost Components** | **Cost ($ Millions)** |
| Admin Costs | 3.16 |
| Central Lab | 3.79 |
| Subject Costs | 3.47 |
| Personnel Costs | 8.21 |
| Site Costs | 12.95 |

| Investigators Information | | | |
|---|---|---|---|
| Name | Brendan D Curti | Role | Principal Investigator |
| Specialty | Internal Medicine; Medical Oncology; Oncology | Board Certification | |
| Primary Designation | Endowed Chair | Associated Organization | Providence Health & Services |
| Contact Number | 1-503-2155696; 1-503-2156494 | Email | brendan.curti@providence.org; bcurti118130@oc.providencedirect.org |
| State | Oregon | Country | United States |

**Similar studies done by Investigator**

| Investigators Information | | | |
|---|---|---|---|
| Name | Anna C Pavlick | Role | Co-Author |
| Specialty | Hematology; Medical Oncology; Internal Medicine; Osteopathy | Board Certification | |
| Primary Designation | Professor | Associated Organization | Weill Cornell Medical College |
| Contact Number | 1-646-9626444; 1-212-7464007; 1-646-6988787; 1-646-9626200 | Email | acp9008@med.cornell.edu |
| State | New York | Country | United States |

**Similar studies done by Investigator**

| Investigators Information | | | |
|---|---|---|---|
| Name | Pippa G Corrie | Role | Co-Author |
| Specialty | Medical Oncology | Board Certification | |
| Primary Designation | Associate Lecturer | Associated Organization | University of Cambridge |
| Contact Number | 44-1223-216083; 44-1223-631776; 44-1223-767600 | Email | pippa.corrie@addenbrookes.nhs.uk; philippa.corrie@nhs.net |
| State | Cambridgeshire | Country | United Kingdom |

**Similar studies done by Investigator**

| Investigators Information | | | |
|---|---|---|---|
| Name | Jose Lutzky | Role | Principal Investigator |
| Specialty | Hematology; Internal Medicine; Medical Oncology; Oncology | Board Certification | |
| Primary Designation | Professor | Associated Organization | University of Miami |

| | | | |
|---|---|---|---|
| Contact Number | 1-305-6896500; 1-305-2844323; 1-786-2088076 | Email | jxl810@miami.edu |
| State | Florida | Country | United States |

**Similar studies done by Investigator**

| **Investigators Information** | | | |
|---|---|---|---|
| Name | Jeffrey S Weber | Role | Co-Author |
| Specialty | Internal Medicine; Medical Oncology; Oncology; Hematology | Board Certification | |
| Primary Designation | Professor | Associated Organization | NYU Robert I. Grossman School of Medicine |
| Contact Number | 1-212-7316160; 1-212-7316262; 1-212-2639333 | Email | jeffrey.weber2@nyumc.org |
| State | New York | Country | United States |

**Similar studies done by Investigator**

**Location(s) (67)**

| Region | Country | State | Trial Site | Address | Status |
|---|---|---|---|---|---|
| Europe | France | | Gustave Roussy Institute | Gustave Roussy Cancer Campus, Villejuif Cedex, Ile-de-france, France, 94805 | Completed |
| Europe | France | Limousin | CHU Dupuytren | Hopital Dupuytren, Limoges cedex, Limousin, France, 87042 | Completed |
| Europe | France | Rhone-Alpes | Centre Hospitalier Lyon Sud | Centre Hospitalier Lyon Sud, | Completed |

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|---|---|---|---|---|---|
| | | | | Pierre-Benite, Rhone-alpes, France, 69495 | |
| Europe | France | Rhone-Alpes | Centre Leon Berard | Centre Leon Berard, Lyon, Rhone-alpes, France, 69008 | Completed |
| Europe | Germany | | Universitatsklinikum Erlangen | Universitatsklinikum Erlangen, Erlangen, Bayern, Germany, 91052 | Completed |
| Europe | Germany | | Universitatsklinikum Halle | Universitatsklinikum Halle, Halle/Saale, Sachsen-anhalt, Germany, 06120 | Completed |
| Europe | Germany | | Wurzburg University Hospital | Universitatsklinikum Wurzburg, Wurzburg, Germany, 97080 | Completed |
| Europe | Germany | | Klinikum rechts der Isar Technical University of Munich | Klinikum Rechts der Isar der Technischen Universitat Munchen, Munchen, Bayern, Germany, 81675 | Completed |
| Europe | Germany | | University Medical Center Schleswig-Holstein | Universitatsklinikum Schleswig-Holstein - Campus Lubeck, | Completed |

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|---|---|---|---|---|---|
| | | | | Lubeck, Schleswig-holstein, Germany, 23538 | |
| Europe | Germany | Baden-wuerttemberg | Heidelberg University Hospital | Universitaetsklinikum Heidelberg, Heidelberg, Baden-wuerttemberg, Germany, 69120 | Completed |
| Europe | Germany | Baden-Wuerttemberg | Universitatskliniku m Tubingen | Universitaetsklinikum Tuebingen (UKT) - Suedwestdeutschen Tumorzentrum - Zentrum fur Neuroonkologie, Tubingen, Baden-wuerttemberg, Germany, 72076 | Completed |
| Europe | Germany | Bavaria | Wurzburg University Hospital | Universitatsklinikum Wurzburg, Wurzburg, Bavaria, Germany, 97080 | Completed |
| Europe | Germany | Sachsen | University Hospital Leipzig | Universitatsklinikum Leipzig, Leipzig, Sachsen, Germany, 4103 | Completed |
| Europe | Germany | Sachsen | University Hospital Carl Gustav Carus | Universitatsklinikum Carl Gustav Carus, | Completed |

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|---|---|---|---|---|---|
| | | | Dresden | Dresden, Sachsen, Germany | |
| Europe | Hungary | | University of Szeged | Szegedi Tudomanyegyetem Szent-Gyorgyi Albert Klinikai Kozpont, Szeged, Csongrad, Hungary, 6720 | Completed |
| Europe | Hungary | Central Hungary | Semmelweis University | Semmelweis Egyetem, Budapest, Central Hungary, Hungary, 1085 | Withdrawn |
| Europe | Italy | Emilia-Romagna | Istituto Scientifico Romagnolo per lo Studio e la cura dei Tumori Srl | Istituto Scientifico Romagnolo per lo Studio e la Cura dei Tumori, Meldola, Forli-cesena, Italy, 47014 | Completed |
| Europe | Italy | Milan | European Institute of Oncology | Istituto Europeo di Oncologia, Milano, Italy, 20141 | Completed |
| Europe | Italy | Naples | Istituto Nazionale Tumori Fondazione Pascale | Istituto Nazionale Tumori IRCCS Fondazione Pascale, Napoli, Italy, 80131 | Completed |
| Europe | Italy | Naples | Istituto Nazionale Tumori Fondazione Pascale | Istituto Nazionale Tumori IRCCS Fondazione | Completed |

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|---|---|---|---|---|---|
| | | | | Pascale, Napoli, Naples, Italy, 80131 | |
| Europe | Italy | Pordenone | Centro di Riferimento Oncologico di Aviano | Centro di Riferimento Oncologico di Aviano, Aviano, Pordenone, Italy, 33081 | Completed |
| Europe | Italy | Torino | Candiolo Cancer Institute | Istituto di Candiolo - Fondazione del Piemonte per l'Oncologia, Candiolo, Torino, Italy, 10060 | Completed |
| Europe | Spain | | University General Hospital Valencia | CONSORCIO HOSPITAL GENERAL UNIVERSITARIO DE VALENCIA | Completed |
| Europe | Spain | | Consorci Hospital General Universitari de Valencia | Consorci Hospital General Universitari de Valencia, Valencia, València, Spain | Completed |
| Europe | Spain | Barcelona | Hospital Clinic i Provincial de Barcelona | Hospital Clinic de Barcelona, Barcelona, Barcelona, Spain, 08036 | Completed |
| Europe | Spain | Barcelona | Vall d'Hebron University Hospital | Hospital Universitari Vall d'Hebron, Barcelona, Barcelona, | Completed |

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|---|---|---|---|---|---|
| | | | | Spain, 08035 | |
| Europe | Spain | Barcelona | Institut Catala d'Oncologia | Institut Catala d'Oncologia, Barcelona, Barcelona, Spain, 08907 | Completed |
| Europe | Spain | Madrid | Hospital Gregorio Maranon | Hospital General Universitario Gregorio Maranon, Madrid, Madrid, Spain, 28007 | Completed |
| Europe | Spain | Madrid | Hospital Universitario 12 de Octubre | Hospital 12 de Octubre, Madrid, Madrid, Spain, 28041 | Completed |
| Europe | Spain | Madrid | Centro Integral Oncologico Clara Campal | HM Centro Integral Oncologico Clara Campal, Madrid, Madrid, Spain, 28050 | Completed |
| Europe | Spain | Madrid | Quironsalud Madrid University Hospital | HOSPITAL QUIRÓNSALUD MADRID, MADRID | Completed |
| Europe | Spain | Madrid | Quironsalud Madrid University Hospital | Hospital Universitario Quironsalud Madrid, Madrid, Madrid, Spain, 28233 | Completed |
| Europe | Spain | Navarra | Clinica Universidad de Navarra | Clinica Universidad de Navarra, Pamplona, Navarra, | Completed |

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|---|---|---|---|---|---|
| | | | | Spain, 31008 | |
| Europe | Switzerland | Bern | University Hospital Inselspital Berne | Inselspital, Bern, Bern, Switzerland, 3010 | Completed |
| Europe | Switzerland | Vaud | Lausanne University Hospital | Centre Hospitalier Universitaire Vaudois Lausanne - Centre Pluridisciplinaire d'Oncologie, Lausanne, Vaud, Switzerland | Completed |
| Europe | United Kingdom | | The Royal Marsden NHS Foundation Trust | Royal Marsden NHS Trust, London, England, United Kingdom, SW3 6JJ | Completed |
| Europe | United Kingdom | Cambridgeshire | Addenbrooke's Hospital | Addenbrooke's Hospital, Cambridge, Cambridgeshire, United Kingdom, CB2 0QQ | Completed |
| Europe | United Kingdom | England | Sarah Cannon Research Institute UK Ltd | Sarah Cannon Research Institute London, London, England, United Kingdom, W1G 6AD | Completed |
| Europe | United Kingdom | Scotland | Beatson West of Scotland Cancer Centre | Beatson West of Scotland Cancer Centre, Glasgow, | Completed |

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|---|---|---|---|---|---|
| | | | | Scotland, United Kingdom, G12 0YN | |
| North America | United States | | David Geffen School of Medicine at UCLA | University of California Los Angeles - David Geffen School of Medicine - Westwood Rheumatology, Los Angeles, California, United States, 90095 | Completed |
| North America | United States | | University of Miami | University of Miami, Miami, Florida, United States, 33136 | Completed |
| North America | United States | California | UCLAs Jonsson Comprehensive Cancer Center | UCLA / Jonsson Comprehensive Cancer Center, Los Angeles, California | Completed |
| North America | United States | California | The Angeles Clinic and Research Institute | The Angeles Clinic and Research Institute, Los Angeles, California, United States, 90048 | Completed |
| North America | United States | California | UC San Diego Moores Cancer Center | University of California San Diego Moores Cancer Center, La Jolla, California, United States, 92093 | Completed |

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|---|---|---|---|---|---|
| North America | United States | California | California Pacific Medical Center | California Pacific Medical Center, San Francisco, California, United States, 94115 | Completed |
| North America | United States | Colorado | University of Colorado Cancer Center | University of Colorado Cancer Center, Aurora, Colorado, United States, 80049 | Completed |
| North America | United States | Connecticut | Yale Cancer Center | Yale Cancer Center, New Haven, Connecticut, United States, 06510 | Completed |
| North America | United States | Florida | H. Lee Moffitt Cancer Center & Research Institute Inc | University of South Florida H. Lee Moffitt Cancer Center and Research Institute, Tampa, Florida, United States, 33612 | Completed |
| North America | United States | Florida | UF Health Cancer Center | University of Florida Health Cancer Center, Orlando, Florida, United States, 32806 | Completed |
| North America | United States | Florida | Mount Sinai Medical Center | Mount Sinai Comprehensive Cancer Center, Miami Beach, Florida, United States, 33140 | Completed |

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|---|---|---|---|---|---|
| North America | United States | Indiana | Indiana University Melvin and Bren Simon Cancer Center | Indiana University / Melvin and Bren Simon Cancer Center, Indianapolis, Indiana | Completed |
| North America | United States | Indiana | Indiana University | Indiana University, Indianapolis, Indiana, United States, 46202-5116 | Completed |
| North America | United States | Kentucky | James Graham Brown Cancer Center | James Graham Brown Cancer Center, Louisville, Kentucky, United States, 40202 | Completed |
| North America | United States | Minnesota | Masonic Cancer Center | University of Minnesota, Masonic Cancer Center, Minneapolis, Minnesota, United States, 55455 | Completed |
| North America | United States | New Jersey | Atlantic Health System Inc | Atlantic Health System, Morristown, New Jersey, United States, 07960 | Completed |
| North America | United States | New Jersey | Rutgers The State University of New Jersey | Rutgers University, New Brunswick, New Jersey, United States | Completed |
| North America | United States | New York | Perlmutter Cancer Center | Laura and Isaac Perlmutter | Completed |

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|---|---|---|---|---|---|
| | | | | Cancer Center at NYU Langone, New York | |
| North America | United States | New York | VCU Massey Cancer Center | Virginia Commonwealth University / Massey Cancer Center, Richmond, Virginia | Completed |
| North America | United States | New York | NYU Langone Health System | New York University Langone Medical Center, New York, New York, United States, 10016 | Completed |
| North America | United States | New York | Roswell Park Cancer Institute | Roswell Park Cancer Institute, Buffalo, New York, United States, 14263 | Completed |
| North America | United States | Oregon | Providence Cancer Center | Providence Cancer Center Oncology and Hematology Care Clinic, Portland, Oregon, United States, 97213 | Completed |
| North America | United States | Pennsylvania | Thomas Jefferson University | Thomas Jefferson University, Philadelphia, Pennsylvania, United States, 19701 | Completed |
| North America | United States | Pennsylvania | UPMC Hillman Cancer Center | University of Pittsburgh | Completed |

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|---|---|---|---|---|---|
| | | | | Medical Center - Hillman Cancer Center, Pittsburgh, Pennsylvania, United States, 15232 | |
| North America | United States | Tennessee | Sarah Cannon Research Institute LLC | Sarah Cannon Research Institute, Nashville, Tennessee, United States | Completed |
| North America | United States | Virginia | Virginia Commonwealth University | Virginia Commonwealth University, Richmond, Virginia, United States, 23298 | Completed |
| North America | United States | Washington | Seattle Cancer Care Alliance | Seattle Cancer Care Alliance, Seattle, Washington, United States, 98109 | Completed |
| North America | United States | Wisconsin | Medical College of Wisconsin | Medical College of Wisconsin, Milwaukee, Wisconsin, United States, 53226 | Completed |

| **Investigator Affiliated Site(s)(140)** | | | | | |
|---|---|---|---|---|---|
| **Region** | **Country** | **State** | **Trial Site** | **Address** | **Status** |
| North America | United States | Texas | Baylor College of Medicine | One Baylor Plaza, Houston, Texas 77030 | |
| North America | United States | California | Cedars-Sinai | 11818 | |

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|---|---|---|---|---|---|
| | | | Medical Center | Wilshire Blvd #200, Los Angeles, CA 90025 | |
| North America | United States | California | Cedars-Sinai Medical Center | 8700 Beverly Blvd, Los Angeles, CA 90048 | |
| North America | United States | Pennsylvania | Children's Hospital of Pittsburgh of UPMC | One Children's Hospital Drive 4401 Penn Ave. Pittsburgh, PA 15224 | |
| North America | United States | Virginia | Children's Hospital of Richmond at VCU | 1250 East Marshall Street, Richmond, Virginia 23298 | |
| North America | United States | New Jersey | Chilton Hospital | 97 West Parkway, Pompton Plains, NJ 07444 | |
| North America | United States | Ohio | Cleveland Clinic | 9500 Euclid Avenue, Cleveland, Ohio 44195 | |
| North America | United States | New Hampshire | Dartmouth-Hitchcock Medical Center | One Medical Center Drive Lebanon, NH 03756 | |
| North America | United States | Florida | Florida Hospital Cancer Institute | 110 W. Underwood Street, Suite AOrlando, FL 32806 | |
| North America | United States | Florida | Florida State University College of Medicine | 3331 Capital Oaks Drive, Tallahassee, FL, 32308 | |

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|---|---|---|---|---|---|
| North America | United States | Washington | Fred Hutchinson Cancer Research Center | 1100 Fairview Ave. N., Seattle, WA 98109 | |
| North America | United States | Washington | Fred Hutchinson/University of Washington Cancer Consortium | 1100 Fairview Ave. N., Seattle, WA 98109 | |
| North America | United States | New Hampshire | Frisbie Memorial Hospital | 11 Whitehall Road, Rochester, NH 03867 | |
| North America | United States | Pennsylvania | Heritage Valley Health System | 1000 Dutch Ridge Road Beaver, PA 15009 | |
| North America | United States | Florida | Holy Cross Hospital Inc | 4725 North Federal HighwayFort Lauderdale, FL 33308 | |
| North America | United States | Florida | Jupiter Medical Center Inc | 1210 S. Old Dixie Hwy, Jupiter, FL 33458 | |
| North America | United States | California | Keck Medicine of USC | 1500 San Pablo St, Los Angeles, CA, 90033 | |
| North America | United States | California | Keck Medicine of USC | 500 Virgil Ave, Los Angeles, CA 90020 | |
| North America | United States | California | Keck Medicine of USC | 625 S Fair Oaks Ave, Pasadena, CA, 91105 | |
| North America | United States | California | Keck School of Medicine of the University of Southern | 1975 Zonal Ave., Los Angeles, CA 90033 | |

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|---|---|---|---|---|---|
| | | | California | | |
| North America | United States | California | Los Angeles County+USC Medical Center | 2051 Marengo Street, Los Angeles, CA 90033 | |
| North America | United States | Pennsylvania | Magee-Womens Hospital of UPMC | 300 Halket St., Pittsburgh, PA 15213 | |
| North America | United States | Florida | Memorial Regional Hospital | 3501 Johnson Street, Hollywood, FL 33021 | |
| North America | United States | New York | New York University College Of Dentistry | 345 E. 24th Street (corner of First Avenue), New York, NY 10010 | |
| North America | United States | New York | New York University School of Medicine | 530 First Avenue Suite 10Q New York, NY 10016 | |
| North America | United States | New Hampshire | Norris Cotton Cancer Center | Barbara E. Rubin Building, One Medical Center Drive, Lebanon, NH 03756 | |
| North America | United States | Washington | Northwest Hospital & Medical Center | 1550 N 115th St, Seattle, WA, 98133 | |
| North America | United States | New Jersey | Overlook Hospital | 99 Beauvoir Ave, Summit, NJ 07902 | |
| North America | United States | Oregon | Providence Health & Services | 4400 NE Halsey St.Portland, OR 97213 | |
| North America | United States | Oregon | Providence | 4805 NE | |

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|---|---|---|---|---|---|
| | | | Portland Medical Center | Glisan St., Portland, OR, 97213 | |
| North America | United States | California | San Francisco Oncology Associates Medical Group | 2100 Webster Street, Suite 326 San Francisco, CA 94115 | |
| North America | United States | Washington | Seattle Children's Hospital | 1900 Ninth Ave., Seattle, WA 98101 | |
| North America | United States | Pennsylvania | Shadyside Hospital Foundation | 532 S Aiken Ave # 302, Pittsburgh, PA, 15232 | |
| North America | United States | Connecticut | Smilow Cancer Hospital | 111 Beach Road Fairfield, CT 06824 | |
| North America | United States | Connecticut | Smilow Cancer Hospital | 114 Woodland Street Hartford, CT 06105 | |
| North America | United States | Connecticut | Smilow Cancer Hospital | New Haven, Connecticut, 06510, United States | |
| North America | United States | Pennsylvania | St. Luke's University Health Network | 1872 St. Luke’s Boulevard, Easton, PA, 18045 | |
| North America | United States | Pennsylvania | St. Luke's University Health Network | 801 Ostrum Street, Bethlehem, PA 18015 | |
| North America | United States | New Jersey | Summit Health | 140 Park Avenue, Florham Park, NJ 07932 | |
| North America | United States | California | Sutter Health | 1350 South Eliseo | |

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| | | | | DriveGreenbrae, CA 94904 | |
| North America | United States | Oregon | The Oregon Clinic | Portland, Oregon, 97213, United States | |
| North America | United States | Ohio | UC Health | 3235 Eden Avenue, CARE/Crawley Building Suite E-870, Cincinnati, OH 45267 | |
| North America | United States | Nevada | UC San Diego Health System | Las Vegas, Nevada, 89135, United States | |
| North America | United States | Pennsylvania | Uniontown Hospital | 500 West Berkeley Street, Uniontown, PA, 15401 | |
| North America | United States | New York | University at Buffalo | 77 Goodell Street Buffalo, NY, USA 14203 | |
| North America | United States | California | University of California Los Angeles | 1147 Murphy Hall, Box 951436, Los Angeles, CA, 90095 | |
| North America | United States | California | University of California San Diego | 6256 Greenwich Drive, San Diego, CA 92122 | |
| North America | United States | California | University of California San Diego | 9500 Gilman Dr., La Jolla, CA 92093 | |
| North America | United States | California | University of California San | 8950 Villa La Jolla Drive, | |

| | | | | | |
|---|---|---|---|---|---|
| | | | Diego School of Medicine | Suite B225, La Jolla, CA, 92037 | |
| North America | United States | California | University of California San Diego School of Medicine | 9500 Gilman Drive, La Jolla, CA, 92093 | |
| North America | United States | Florida | University of Central Florida College of Medicine | 6850 Lake Nona Blvd. Orlando, Fl 32827 | |
| North America | United States | Kentucky | University of Louisville | 550 South Jackson Street 3rd Floor Louisville, Kentucky 40202 | |
| North America | United States | Kentucky | University of Louisville Physicians Inc | 300 E. Market St., Suite 400, Louisville, KY 40202 | |
| North America | United States | Kentucky | University of Louisville School of Medicine | 323 East Chestnut Street Louisville, KY 40202 | |
| North America | United States | Florida | University of Miami Health System | Miami, Florida, 33136, United States | |
| North America | United States | Minnesota | University of Minnesota | 3 Morrill Hall 100 Church St. S.E. Minneapolis MN 55455 | |
| North America | United States | Pennsylvania | University of Pittsburgh | 230 McKee Place, Suite 600 Pittsburgh, PA 15213 | |
| North America | United States | Pennsylvania | University of Pittsburgh Medical Center | 5230 Centre Ave. Pittsburgh, PA 15232 | |

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|---|---|---|---|---|---|
| North America | United States | Pennsylvania | University of Pittsburgh Medical Center | Falk Medical Building Seventh Floor 3601 Fifth Ave. Pittsburgh, PA 15213 | |
| North America | United States | Pennsylvania | University of Pittsburgh School of Medicine | S530 Scaife Hall 3550 Terrace Street Pittsburgh, PA 15261 | |
| North America | United States | Florida | University of South Florida | 3702 Spectrum Blvd. Ste. 165, Tampa, FL 33612 | |
| North America | United States | Texas | University of Texas MD Anderson Cancer Center | 1515 Holcombe Blvd., Houston, Texas 77030 | |
| North America | United States | Washington | University of Washington School of Medicine | 1959 N.E. Pacific St., Seattle, WA 98195 | |
| North America | United States | Pennsylvania | UPMC CancerCenter | 100 Fairfield Drive, Seneca, PA 16346 | |
| North America | United States | Pennsylvania | UPMC CancerCenter | 1500 Fifth Avenue, D Level, McKeesport, PA 15132 | |
| North America | United States | Pennsylvania | UPMC CancerCenter | 200 Village Drive, Greensburg, PA 15601 | |
| North America | United States | Pennsylvania | UPMC CancerCenter | 5115 Centre Avenue, Pittsburgh, PA 15232 | |

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|---|---|---|---|---|---|
| North America | United States | California | USC Norris Comprehensive Cancer Center | 1441 Eastlake Avenue, Los Angeles, CA 90033 | |
| North America | United States | California | USC Norris Comprehensive Cancer Center | 1441 Eastlake Avenue, Suite 8302, Los Angeles, CA 90089 | |
| North America | United States | Washington | UW Medical Center | Campus Box 358050, Seattle WA 98195 | |
| North America | United States | Tennessee | Vanderbilt University | 5824 Stevenson Center Nashville, TN 37232 | |
| North America | United States | Tennessee | Vanderbilt University Medical Center | 1211 Medical Center Drive, Nashville, TN 37232 | |
| North America | United States | Tennessee | Vanderbilt-Ingram Cancer Center | 2220 Pierce Avenue, Nashville, TN 37232 | |
| North America | United States | New York | Veterans Affairs Medical Center | 3495 Bailey Avenue, Buffalo, NY 14215 | |
| North America | United States | Vermont | Veterans Affairs Medical Center | White River Junction, Vermont, 05009, United States | |
| North America | United States | Florida | Westside Center for Clinical Research LLC | 810 Lane Avenue South, Jacksonville, FL 32205 | |
| North America | United States | Connecticut | Yale University | New Haven, CT 06520 | |

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|---|---|---|---|---|---|
| North America | United States | Connecticut | Yale New Haven Hospital Inc | 20 York Street New Haven, CT 06510 | |
| North America | United States | New York | Memorial Sloan Kettering Cancer Center | 1275 York Avenue, New York, NY 10065 | |
| North America | United States | New York | NewYork-Presbyterian Hospital | 5141 Broadway, New York, NY 10034 | |
| North America | United States | Florida | Orlando Health Inc | 52 W Underwood St, Orlando, FL 32806 | |
| North America | United States | New Jersey | Rutgers Cancer Institute of New Jersey | 195 Little Albany Street, New Brunswick, NJ 08903 | |
| North America | United States | Pennsylvania | Thomas Jefferson University Hospitals | 132 South 10th Street, Philadelphia, PA 19107 | |
| North America | United States | Colorado | University of Colorado | 13001 East 17th Place, Aurora, CO 80045 | |
| North America | United States | Colorado | University of Colorado Hospital | Aurora, Colorado, 80045, United States | |
| North America | United States | Florida | University of Miami Sylvester Comprehensive Cancer Center | 1192 E. Newport Center Drive, Suite 100 Deerfield Beach, FL 33442 | |
| North America | United States | Florida | University of Miami Sylvester | 1475 N.W. 12th Avenue, | |

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|---|---|---|---|---|---|
| | | | Comprehensive Cancer Center | Miami, Florida 33136 | |
| North America | United States | Florida | University of Miami Sylvester Comprehensive Cancer Center | 2801 NE 213th Street, Suite 1101, Aventura, FL 33180 | |
| North America | United States | Florida | University of Miami Sylvester Comprehensive Cancer Center | 5555 Ponce de Leon Boulevard Coral Gables, FL 33146 | |
| North America | United States | Florida | University of Miami Sylvester Comprehensive Cancer Center | 8100 SW 10th St, Plantation, FL 33324 | |
| North America | United States | Florida | University of Miami Sylvester Comprehensive Cancer Center | 8932 S.W. 97th Ave Miami, FL 33176 | |
| North America | United States | New York | Weill Cornell Medical College | 1305 York Ave, 5 th Floor New York, NY 10021 | |
| North America | United States | Connecticut | Yale University School of Medicine | 15 York St, New Haven, CT, 06520 | |
| North America | United States | Connecticut | Yale University School of Medicine | 333 Cedar Street New Haven, CT 06510 | |
| North America | United States | Pennsylvania | John P. Murtha Regional Cancer Center | 337 Somerset Street, Johnstown, PA, 15901 | |
| North America | United States | Texas | Lester and Sue Smith Breast Center | Baylor Plaza, Houston, Texas 77030 | |
| North America | United States | Colorado | Memorial Hospital Cancer Center | 525 Bob Peters Grove, Memorial | |

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|---|---|---|---|---|---|
| | | | | Medical Building, Suite 202 Colorado Springs, CO 80909 | |
| North America | United States | New Jersey | Morristown Medical Center Family Medicine | 435 South Street, Suite 220A, Morristown, NJ, 07960 | |
| North America | United States | Florida | Mount Sinai Comprehensive Cancer Center | 4306 Alton Rd, Miami Beach, FL 33140, United States | |
| North America | United States | Florida | MSMC Research Program | 4306 ALTON ROAD, THIRD FLOOR, MIAMI BEACH, FL 33140 | |
| North America | United States | Maryland | National Cancer Institute US | 9000 Rockville Pike, Bethesda, MD 20892 | |
| North America | United States | Colorado | Poudre Valley Hospital | 1024 S. Lemay Avenue, Fort Collins, CO 80524 | |
| North America | United States | Colorado | University of Colorado Hospital Anschutz Cancer Pavilion | 1665 Aurora Court, Aurora, CO 80045 | |
| North America | United States | Pennsylvania | UPMC Passavant | 9100 Babcock Blvd, Pittsburgh, PA, 15237 | |
| North America | United States | Pennsylvania | UPMC Presbyterian | 450 Melwood Avenue – Lower Level, Pittsburgh, PA, | |

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| | | | | 15213 | |
| North America | United States | Pennsylvania | UPMC St. Margaret | 815 Freeport Road Pittsburgh, PA 15215 | |
| North America | United States | California | USC Norris Oncology/Hematology Newport Beach | Newport Beach, California, 92663, United States | |
| North America | United States | California | USC Verdugo Hills Hospital | 501 South Buena Vista Street , Burbank, CA 91505 | |
| North America | United States | California | VA San Diego Healthcare System | 3350 La Jolla Village Dr. San Diego, CA 92161 | |
| North America | United States | Tennessee | Vanderbilt-Ingram Cancer Center Franklin | 1025 Westhaven Blvd. Suite 100 Franklin, TN 37064 | |
| North America | United States | Virginia | VCU Health | 1250 E Marshall St, Richmond, VA, 23298 | |
| Middle East and Africa | Israel | Jerusalem | Hadassah Medical Center | Kiryat Hadassah, pob 12000 Jerusalem, 91120, Israel | |
| Europe | Hungary | Csongrád | Albert Szent Gyorgyi Clinical Center | 6720 Szeged, Korányi fasor 6. | |
| Europe | Hungary | Csongrád | Albert Szent Gyorgyi Clinical Center | Tisza Lajos krt. 107, H-6725, Szeged | |
| Europe | United Kingdom | England | Cambridge University | Hills Road, Cambridge, | |

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| | | | Hospitals NHS Foundation Trust | CB2 0QQ | |
| Europe | Greece | Attica | General Hospital of Athens Elpis | Dimitsanas 7, Athina 115 22, Greece | |
| Europe | Greece | Attica | General State Hospital of Athens | Athens, Attica, Greece, 11527 | |
| Europe | United Kingdom | England | Institute of Cancer Research | Sutton, England, SM25NG, United Kingdom | |
| Europe | Greece | Attica | Laikon General Hospital | Thoma 17, PC 11527, Athens | |
| Europe | United Kingdom | England | University College London | Gower Street London WC1E 6BT | |
| Europe | United Kingdom | England | University College London Hospitals | London, England, NW12BU, United Kingdom | |
| Europe | Greece | Attica | University of Athens | Athens, Attica, 11527, Greece | |
| Europe | United Kingdom | England | University of Cambridge | Cambridge, CB2 0QQ | |
| Europe | Germany | Schleswig-Holstein | University of Lubeck | Ratzeburger Allee 160, 23562 | |
| Europe | Spain | Navarra | University of Navarra | C/ Irunlarrea 1. 31008 Pamplona. Navarra (España) | |
| Europe | France | Ile de France | University of Paris-Sud | Siège et Présidence Bât. 300 - 91405 Orsay cedex I FRANCE | |

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| Asia-Pacific | Australia | New South Wales | Prince of Wales Private Hospital | Barker Street, Randwick NSW 2031 | |
| Europe | United Kingdom | England | HCA Healthcare UK Ltd | London, England, W1G6AD, United Kingdom | |
| Europe | France | Auvergne-Rhone-Alpes | Hospices Civils de Lyon | 165, Chemin du Grand Revoyet - 69310 Pierre Benite | |
| Europe | Hungary | Budapest | Szent Margit Hospital | 1032 Budapest, Bécsi út 132 | |
| North America | United States | Missouri | Capital Regional Medical Center in Jefferson City | Jefferson City, Missouri, 65109, United States | |
| North America | United States | Colorado | UCHealth Memorial Hospital Central | 1400 E. Boulder Street, Colorado Springs, CO 80909 | |
| North America | United States | Pennsylvania | UPMC Susquehanna | 700 High Street, Williamsport, PA 17701 | |
| North America | United States | New York | Weill Cornell Medicine | 1300 York Avenue . New York, NY 10065 | |
| North America | United States | Kentucky | University of Louisville Hospital | 530 S Jackson Street, Louisville, KY 40202 | |
| North America | United States | New York | NYU Langone Health | 550 First Avenue, New York, NY 10016 | |

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|---|---|---|---|---|---|
| Europe | United Kingdom | England | Bupa Foundation | 1 Angel Ct, London EC2R 7HJ, United Kingdom | |
| Asia-Pacific | India | Karnataka | George Clinical Pty Ltd | Plot No 5, 12th Floor Prestige Khoday Towers, Raj Bhavan Road, Bangalore, 560001 India | |
| North America | United States | Virginia | Stony Point Surgery Center | 8700 Stony Point Pkwy, Suite 100, Richmond, VA 23235 | |
| North America | United States | California | California Research Institute | 1300 N Vermont Ave, Suite 606, Los Angeles, CA 90027 | |

**Contact Detail(s)**

| Contact Person Name | Phone Number | Email ID | Address | State | Country | Region |
|---|---|---|---|---|---|---|
| Susie Tanamly | +16502607120240, +34 900 811 335 | c14401.melanoma@iovance.com | Iovance Biotherapeutics, Inc., 999 Skyway Road, Suite 150, San Carlos, 94070, United States | California | United States | North America |
| Matthew Madura | 203-737-5381 | matthew.madura@yale.edu | Yale University, New haven | Connecticut | United States | North America |
| Erica Royster | 813-745-4279 | erica.royster@moffitt.org | Moffitt Cancer Center, Tampa, Florida | Florida | United States | North America |

**Site Coordinator Detail(s)**

| Site Coordinator | Email | Phone | Address | Organization | Site Name |
|---|---|---|---|---|---|

| Name | | | | | |
|---|---|---|---|---|---|
| Matthew Madura | matthew.madura@yale.edu | 203-737-5381 | Yale University, New haven | Yale University | Yale University, New Haven, 06520 |
| Erica B Royster | erica.royster@moffitt.org | 813-745-4279 | Moffitt Cancer Center, Tampa, Florida | H. Lee Moffitt Cancer Center & Research Institute Inc | H. Lee Moffitt Cancer Center & Research Institute Inc, Tampa, 33612 |

**Key Trial Events (112)**

| Event Date | Event Brief | Event Type | Source |
|---|---|---|---|
| 16 Feb 2024 | FDA Approves First Cellular Therapy to Treat Patients with Unresectable or Metastatic Melanoma | Trial Update | https://www.prnewswire.com/news-releases/fda-approves-first-cellular-therapy-to-treat-patients-with-unresectable-or-metastatic-melanoma-302064424.html |
| 16 Feb 2024 | Iovance's AMTAGVI (lifileucel) Receives U.S. FDA Accelerated Approval for Advanced Melanoma Results Updated | Results | https://ir.iovance.com/news-releases/news-release-details/iovances-amtagvitm-lifileucel-receives-us-fda-accelerated |
| 06 Dec 2023 | Long-term Efficacy and Patterns of Response of Lifileucel Tumor-infiltrating Lymphocyte (Til) Cell Therapy in Patients with Advanced Melanoma: A 4-year Analysis of the C-144-01 Study Trial results updated. | Results | https://cslide.ctimeetingtech.com/immuno23hybrid/attendee/confcal/show/session/10 |
| 07 Nov 2023 | Iovance Biotherapeutics Reports Third Quarter and Year-to-Date 2023 Financial Results and Corporate Updates | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-third-quarter-and-year-date-2023 |
| 01 Nov 2023 | Long-term Efficacy and Safety of Lifileucel Tumor-infiltrating Lymphocyte (Til) Cell Therapy in Patients with Advanced Melanoma: A 4-year Analysis of the C-144–01 Study Trial results are updated. | Results | https://jitc.bmj.com/content/11/Suppl_1/A873 |

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| 31 Oct 2023 | Iovance Biotherapeutics to Present Clinical and Pre-clinical Data for Tumor Infiltrating Lymphocyte (TIL) Therapies at (SITC) 38th Annual Meeting | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-present-clinical-and-pre-clinical-data-0 |
| 20 Oct 2023 | As per the second quarter and first half 2023 financial results and corporate updates August 2023, study results expected to be presented at European Society for Medical Oncology (ESMO CONGRESS) 2023, October 20-24, 2023, Madrid, Spain. | Results | https://ir.iovance.com/node/13881/pdf (Page No: 02) |
| 20 Oct 2023 | Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy in Patients (Pts) with Advanced Mucosal Melanoma after Progression on Immune Checkpoint Inhibitors (ICI): Results from the Phase II C-144-01 Study Results updated | Results | https://cslide.ctimeetingtech.com/esmo2023/attendee/confcal/presentation/list?q=1086MO&r=st%7E9 |
| 16 Oct 2023 | Iovance Biotherapeutics Announces Clinical Data for Lifileucel in Advanced Mucosal Melanoma at the European Society for Medical Oncology Congress Results updated | Results | https://www.globenewswire.com/news-release/2023/10/16/2760639/0/en/Iovance-Biotherapeutics-Announces-Clinical-Data-for-Lifileucel-in-Advanced-Mucosal-Melanoma-at-the-European-Society-for-Medical-Oncology-ESMO-Congress.html |
| 20 Jun 2023 | Iovance Biotherapeutics to Host Virtual Roundtable With Key Opinion Leaders to Discuss Melanoma Treatment Landscape | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-host-virtual-roundtable-key-opinion |
| 29 May 2023 | FDA accepts Iovance's BLA for melanoma therapy lifileucel | Trial Update | https://www.pharmaceutical-technology.com/news/fda-iovance-bla-melanoma-ifileucel/ |
| 23 Apr 2023 | Efficacy and Safety of Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy in Patients with Advanced | Results | https://ebmt2023.abstractserver.com/program/#/details/presentations/963 |

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| | Melanoma Enrolled in Consecutive Cohorts of the C-144-01 Study Trial results updated | | |
| 27 Mar 2023 | Iovance submits lifileucel BLA to US FDA | Trial Update | https://www.pharmaceutical-technology.com/news/iovance-submits-lifileucel-bla-to-us-fda/ |
| 25 Mar 2023 | Lifleucel TIL Cell Therapy in Patients with Advanced Melanoma After Progression on Immune Checkpoint Inhibitors (ICI) Andbtargeted Therapy: Tumor Tissue Procurement Data from the C-144-01 Study Trial results updated | Results | https://link.springer.com/content/pdf/10.1245/s10434-023-13332-7.pdf?pdf=inline%20link |
| 24 Feb 2023 | Iovance Biotherapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Corporate Updates | Trial Update | https://www.globenewswire.com/news-release/2023/02/28/2617634/0/en/Iovance-Biotherapeutics-Reports-Fourth-Quarter-and-Full-Year-2022-Financial-Results-and-Corporate-Updates.html |
| 15 Feb 2023 | Response to Lifileucel Tumor-infiltrating Lymphocyte (TIL) Cell Therapy after ICI Resistance Regardless of Definition: An Analysis of the C-144-01 Trial in Patients with Advanced Melanoma Trial results are updated. | Results | https://astct-29-s2.elsevierdigitaledition.com/ |
| 31 Dec 2022 | Iovance Biotherapeutics Inc., Corporate Overview Presentation<br>Study cohort 4 data expected in 2022. | Results | https://ir.iovance.com/static-files/efb8f5d3-1eb0-4bc0-baf7-8ff5c54e6dbd |
| 31 Dec 2022 | Iovance Biotherapeutics Inc., Corporate Overview Presentation<br>Study cohort 4 data expected in 2022. | Results | https://ir.iovance.com/static-files/efb8f5d3-1eb0-4bc0-baf7-8ff5c54e6dbd |
| 31 Dec 2022 | Iovance Biotherapeutics Inc., Corporate Overview Presentation Study cohort 4 data expected in 2022. | Results | https://ir.iovance.com/static-files/1fd55821-d1ee-4403-8aa5-7f25f83894b1 |
| 08 Dec 2022 | Number of IL-2 doses and clinical outcomes of tumor-infiltrating lymphocyte (TIL) cell therapy: Post hoc | Results | https://oncologypro.esmo.org/meeting-resources/esmo-immuno-oncology- |

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| | analysis of the C-144-01 trial of lifileucel in patients with advanced melanoma Trial results updated. | | congress/number-of-il-2-doses-and-clinical-outcomes-of-tumor-infiltrating-lymphocyte-til-cell-therapy-post-hoc-analysis-of-the-c-144-01-trial-of-lifileuc |
| 18 Nov 2022 | Iovance Biotherapeutics Provides Update on Biologics License Application Submission for Lifileucel in Advanced Melanoma | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-provides-update-biologics-license |
| 08 Nov 2022 | Lifileucel TIL cell monotherapy in patients with advanced melanoma after progression on immune checkpoint inhibitors (ICI) and targeted therapy: pooled analysis of consecutive cohorts (C-144–01 study) Trial results updated | Results | https://jitc.bmj.com/content/10/Suppl_2/A821 |
| 03 Nov 2022 | Iovance Biotherapeutics Reports Third Quarter and Year-to-Date 2022 Financial Results and Corporate Updates | Trial Update | https://www.globenewswire.com/en/news-release/2022/11/03/2548238/0/en/Iovance-Biotherapeutics-Reports-Third-Quarter-and-Year-to-Date-2022-Financial-Results-and-Corporate-Updates.html |
| 05 Oct 2022 | Iovance Biotherapeutics to present clinical data for lifileucel tumor infiltrating lymphocyte (TIL) therapy in advanced melanoma at Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-present-clinical-data-lifileucel-tumor |
| 10 Sep 2022 | Efficacy and Safety of Lifileucel, an Investigational Autologous Tumor-infiltrating Lymphocyte (TIL) Cell Therapy, in Patients with Advanced Melanoma Previously Treated with Anti-LAG3 Antibody Trial results updated | Results | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano |
| 06 Sep 2022 | Iovance Biotherapeutics to present data on lifileucel at ESMO 2022 | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance- |

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| | | | biotherapeutics-present-posters-esmo-2022 |
| 25 Aug 2022 | Iovance Biotherapeutics initiates biologics license application (BLA) submission for lifileucel in advanced melanoma | Trial Update | https://www.globenewswire.com/news-release/2022/08/25/2504495/0/en/Iovance-Biotherapeutics-Initiates-Biologics-License-Application-BLA-Submission-for-Lifileucel-in-Advanced-Melanoma.html |
| 04 Aug 2022 | Iovance Biotherapeutics Reports Second Quarter and First Half 2022 Financial Results and Corporate Updates | Trial Update | https://www.globenewswire.com/news-release/2022/08/04/2492743/0/en/Iovance-Biotherapeutics-Reports-Second-Quarter-and-First-Half-2022-Financial-Results-and-Corporate-Updates.html |
| 09 Jun 2022 | The Jefferies 2022 Annual Global Healthcare Conference Results updated | Top-line Results | https://wsw.com/webcast/jeff240/iova/1845375 |
| 08 Jun 2022 | Iovance Biotherapeutics to Present at Upcoming Conferences | Trial Update | https://www.globenewswire.com/news-release/2022/06/08/2459172/0/en/Iovance-Biotherapeutics-to-Present-at-Upcoming-Conferences.html |
| 06 Jun 2022 | Tumor Mutational Burden (TMB) in Immune Checkpoint Inhibitor (ICI)-naïve and -experienced Patients with Metastatic Melanoma Treated with Lifileucel, a Tumor-infiltrating Lymphocyte (TIL) Cell Therapy Pooled results updated | Pooled Results | https://meetings.asco.org/abstracts-presentations/210188 |
| 26 May 2022 | Iovance Biotherapeutics announces positive clinical data for Lifileucel in advanced melanoma Result added; Trial Status Changed from "Ongoing, not recruiting" to "Completed" | Results;Trial Status | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data |
| 24 Feb 2022 | Iovance Biotherapeutics Reports Fourth Quarter and Full Year 2021 Financial | Trial Update | https://www.globenewswire.com/news- |

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| | Results and Corporate Updates | | release/2022/02/24/2391884/0/en/Iovance-Biotherapeutics-Reports-Fourth-Quarter-and-Full-Year-2021-Financial-Results-and-Corporate-Updates.html |
| 06 Jun 2021 | Iovance Biotherapeutics announces 33-Month follow up data for Lifileucel in advanced melanoma at ASCO 2021 Annual Meeting | Results | https://www.globenewswire.com/news-release/2021/06/06/2242393/0/en/Iovance-Biotherapeutics-Announces-33-Month-Follow-Up-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html |
| 06 Jun 2021 | Iovance Biotherapeutics announces 33-Month follow up data for Lifileucel in advanced melanoma at ASCO 2021 Annual Meeting | Trial Update | https://www.globenewswire.com/news-release/2021/06/06/2242393/0/en/Iovance-Biotherapeutics-Announces-33-Month-Follow-Up-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html |
| 06 Jun 2021 | ASCO Update Call Trial Results updated | Results | https://ir.iovance.com/static-files/7f1edb46-6a77-4e34-b907-6402f4b5355f |
| 04 Jun 2021 | Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced melanoma: Evaluation of impact of prior anti-PD-1 therapy Trial Results updated | Results | https://meetinglibrary.asco.org/record/196423/abstract |
| 04 Jun 2021 | Iovance Biotherapeutics to present clinical data for Lifileucel in advanced melanoma at ASCO 2021 Annual Meeting Study data expected to be presented at the upcoming ASCO 2021 Annual Meeting, to be held June 4-8, 2021 | Results | https://www.globenewswire.com/news-release/2021/04/28/2218849/0/en/Iovance-Biotherapeutics-to-Present-Clinical-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html |
| 19 May 2021 | Iovance Biotherapeutics announces | Trial Update | https://ir.iovance.com/news- |

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| | clinical data updates for Lifileucel in advanced melanoma at upcoming ASCO 2021 annual meeting | | releases/news-release-details/iovance-biotherapeutics-announces-clinical-data-updates-1 |
| 12 May 2021 | Journal of clinical oncology publishes clinical data for cohort 2 in Iovance C-144-01 study of Lifileucel TIL therapy in metastatic melanoma | Trial Update | https://ir.iovance.com/news-releases/news-release-details/journal-clinical-oncology-publishes-clinical-data-cohort-2 |
| 06 May 2021 | Iovance Biotherapeutics reports first quarter 2021 financial results and corporate updates | Trial Update | https://www.globenewswire.com/news-release/2021/05/06/2224972/0/en/Iovance-Biotherapeutics-Reports-First-Quarter-2021-Financial-Results-and-Corporate-Updates.html |
| 10 Apr 2021 | Lifileucel (LN-144), a cryopreserved autologous tumor infiltrating lymphocyte (TIL) therapy in patients with advanced (unresectable or metastatic) melanoma: durable duration of response at 28 month follow up<br><br>Results updated. | Results | https://www.abstractsonline.com/pp8/#!/9325/presentation/5139 |
| 09 Apr 2021 | Iovance Biotherapeutics announces clinical data updates for lifileucel in advanced melanoma during American Association for Cancer Research (AACR) 2021 Annual Meeting | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-clinical-data-updates-0 |
| 10 Mar 2021 | Iovance Biotherapeutics to present updated clinical data for tumor infiltrating lymphocyte (TIL) therapy Lifileucel in advanced melanoma at American Association for Cancer Research (AACR) 2021 Annual Meeting | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-present-updated-clinical-data-tumor |
| 25 Feb 2021 | Iovance Biotherapeutics reports fourth quarter and full year 2020 financial results and corporate updates Updated Results | Results | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-2 |

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| 14 Jan 2021 | Presented at the Virtual 39th Annual J.P. Morgan Healthcare Conference Results updated. | Results | https://jpmorgan.metameetings.net/events/healthcare21/sessions/35760-iovance-biotherapeutics-inc/webcast?gpu_only=true&kiosk=true (Slides 05,16,17,18,19,20,21,22) |
| 31 Dec 2020 | Corporate presentation Top line data expected in 2020 | Top-line Results | https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f |
| 05 Oct 2020 | Iovance Biotherapeutics provides update for Lifileucel in metastatic melanoma | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-provides-update-lifileucel-metastatic |
| 06 Aug 2020 | Iovance Biotherapeutics reports second quarter 2020 financial results and provides a corporate update | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-second-quarter-2020-financial |
| 29 May 2020 | Iovance presents updated clinical data for tumor infiltrating lymphocyte (TIL) therapy lifileucel in advanced melanoma at ASCO scientific program Result updated | Results | https://ir.iovance.com/news-releases/news-release-details/iovance-presents-updated-clinical-data-tumor-infiltrating |
| 27 May 2020 | Iovance reports pivotal cohort 4 data for Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel from C-144-01 clinical study in advanced Melanoma Trial results updated | Results | https://www.globenewswire.com/news-release/2020/05/27/2039716/0/en/Iovance-Reports-Pivotal-Cohort-4-Data-for-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Lifileucel-from-C-144-01-Clinical-Study-in-Advanced-Melanoma.html |
| 13 May 2020 | Iovance Biotherapeutics announces clinical data updates for Lifileucel in advanced melanoma | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-clinical-data-updates |
| 05 May 2020 | Iovance Biotherapeutics reports first | Trial Update | http://www.globenewswire.c |

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| | quarter 2020 financial results and provides a corporate update | | om/news-release/2020/05/05/2027879/0/en/Iovance-Biotherapeutics-Reports-First-Quarter-2020-Financial-Results-and-Provides-a-Corporate-Update.html |
| 29 Apr 2020 | Iovance Biotherapeutics to present updated data from clinical study in advanced melanoma at ASCO 2020 virtual scientific program | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-present-updated-data-clinical-study |
| 31 Mar 2020 | Iovance Biotherapeutics reports second quarter 2019 financial results and provides corporate update Completion of enrollment in cohort 4 expected in first quarter of 2020. | Enrollment Status | https://www.globenewswire.com/news-release/2019/08/01/1895944/0/en/Iovance-Biotherapeutics-Reports-Second-Quarter-2019-Financial-Results-and-Provides-Corporate-Update.html |
| 25 Feb 2020 | Iovance Biotherapeutics reports fourth quarter and full-year 2019 financial results and provides corporate update cohort 4 of the C-144-01 study was initiated in March 2019 and completed in January 2020. | Trial Update | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-1 |
| 15 Jan 2020 | Iovance Biotherapeutics completes patient dosing in registration-enabling cohort 4 of the C-144-01 melanoma study with Lifileucel Trial Status Changed from "Ongoing, recruiting" to "Ongoing, not recruiting" | Trial Status | https://www.globenewswire.com/news-release/2020/01/15/1970831/0/en/Iovance-Biotherapeutics-Completes-Patient-Dosing-in-Registration-Enabling-Cohort-4-of-the-C-144-01-Melanoma-Study-with-Lifileucel.html |
| 31 Dec 2019 | Houston Oncology Summit Presentation Study IRC data of Cohort 2 expected in fourth quarter of 2019 | Results | http://ir.iovance.com/static-files/47dfc7e0-e16f-4332-b24e-72e53e59c702 |
| 21 Nov 2019 | Iovance Biotherapeutics announces results of a subgroup analysis of patients in the Lifileucel metastatic | Results | http://ir.iovance.com/news-releases/news-release-details/iovance- |

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| | melanoma study who are primary refractory to anti-PD-1/L1 therapy Updated result | | biotherapeutics-announces-results-subgroup-analysis |
| 20 Nov 2019 | Lifileucel (a cryopreserved autologous tumor infiltrating lymphocyte therapy) produces durable responses at one-year median study follow-up in patients with advanced metastatic melanoma previously progressed/ refractory to multiple prior therapies including anti-PD-1 Results updated. | Results | https://registration.sitesolutionsworldwide.com/synergy/v_1_/event_files/Late_Breaking_Abstracts_2019.pdf |
| 08 Nov 2019 | Iovance Biotherapeutics announces updated phase 2 clinical data from the Lifileucel Metastatic Melanoma trial at the Society for Immunotherapy of Cancer 34th Annual Meeting Result reported | Results | http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-updated-phase-2-clinical-0x |
| 04 Nov 2019 | Iovance Biotherapeutics reports third quarter and September year-to-date 2019 financial results | Trial Update | http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-third-quarter-and-september-year |
| 02 Jul 2019 | Iovance Biotherapeutics provides Cervical Cancer Program Updates Following End of Phase 2 Meeting with U.S. Food and Drug Administration (FDA) | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2402832 |
| 05 Jun 2019 | The Jefferies 2019 Global Healthcare Conference<br><br>Trial results updated | Results | http://www.wsw.com/webcast/jeff118/iova/?lobby=true&day=2 |
| 01 Jun 2019 | Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients who progressed on multiple prior therapies including anti-PD-1. Results updated | Results | http://abstracts.asco.org/239/AbstView_239_266867.html |
| 31 May 2019 | Updated results of studies in advanced cervical cancer support long-term efficacy of Iovance tumor infiltrating lymphocyte (TIL) therapy LN-145 | Results | https://www.globenewswire.com/news-release/2019/05/31/1861028/0/en/Updated-Results-of- |

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| | Results updated | | Studies-in-Advanced-Cervical-Cancer-and-Melanoma-Support-Long-Term-Efficacy-of-Iovance-Tumor-Infiltrating-Lymphocyte-TIL-Therapy.html |
| 31 May 2019 | Updated results of studies in melanoma support long-term efficacy of Iovance tumor infiltrating lymphocyte (TIL) therapy lifileucel Results added | Results | https://www.globenewswire.com/news-release/2019/05/31/1861028/0/en/Updated-Results-of-Studies-in-Advanced-Cervical-Cancer-and-Melanoma-Support-Long-Term-Efficacy-of-Iovance-Tumor-Infiltrating-Lymphocyte-TIL-Therapy.html |
| 31 May 2019 | Iovance Biotherapeutics announces expansion of its partnership with WuXi Advanced Therapies Business | Trial Update | https://www.prnewswire.com/news-releases/iovance-biotherapeutics-expands-partnership-with-wuxi-advanced-therapies-business-300859740.html |
| 31 May 2019 | Iovance Biotherapeutics expands partnership with WuXi Advanced Therapies Business | Trial Update | https://www.prnewswire.com/news-releases/iovance-biotherapeutics-expands-partnership-with-wuxi-advanced-therapies-business-300859740.html |
| 15 May 2019 | Iovance Biotherapeutics announces updates to tumor infiltrating lymphocyte (TIL) therapy clinical programs Trial results reported | Results | http://www.globenewswire.com/news-release/2019/05/15/1825697/0/en/Iovance-Biotherapeutics-Announces-Updates-to-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Clinical-Programs.html |
| 07 May 2019 | Iovance Biotherapeutics reports first quarter 2019 financial results and provides corporate update | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2397573 |
| 02 Apr 2019 | Iovance Biotherapeutics announces first | Trial Update | http://ir.iovance.com/phoenix |

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| | patient dosed in Cohort 4 of Pivotal InnovaTIL-01 study of Lifileucel in Metastatic Melanoma First subject dosed in Cohort 4 | | .zhtml?c=254507&p=RssLanding&cat=news&id=2393137 |
| 01 Apr 2019 | Iovance Biotherapeutics presents data at AACR Annual Meeting on T-Cell Diversity and Persistence in patients receiving Tumor Infiltrating Lymphocyte (TIL) Therapy Lifileucel Results added | Results | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2392939 |
| 01 Apr 2019 | Persistence of cryopreserved tumor-infiltrating lymphocyte product lifileucel (LN-144) in C-144-01 study of advanced metastatic melanoma Trial results updated | Results | https://www.abstractsonline.com/pp8/#!/6812/presentation/9204 |
| 29 Mar 2019 | Iovance Biotherapeutics Announces April Scientific and Investor Presentations | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2392771 |
| 01 Mar 2019 | Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients previously treated with at least one prior systemic therapy Trial Results updated | Results | https://meetinglibrary.asco.org/record/170363/abstract |
| 27 Feb 2019 | Iovance Biotherapeutics reports fourth quarter and full-year 2018 financial results and provides corporate update Subject Enrollment Commenced in the Registrational Cohort 4 and last patient was enrolled in Cohort 2 of the metastatic melanoma study in the fourth quarter of 2018 | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2389304 |
| 10 Jan 2019 | The 37th Annual J.P. Morgan Healthcare Conference<br><br>Cohort 2 fully enrolled | Trial Update | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1 |
| 10 Jan 2019 | The 37th Annual J.P. Morgan Healthcare Conference<br><br>Trial results updated, Cohort 2 fully | Results;Trial Update | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4f |

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| | enrolled | | FR5cGU9MQ==&t=1 (Side 04) |
| 07 Nov 2018 | Safety and efficacy of cryopreserved autologous tumor infiltrating lymphocyte therapy (LN-144, lifileucel) in advanced metastatic melanoma patients following progression on checkpoint inhibitors Preliminary results updated | Interim Results | https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-018-0423-x |
| 06 Nov 2018 | Iovance Biotherapeutics announces updated phase 2 clinical data from the Lifileucel metastatic melanoma trial at the Society for Immunotherapy of Cancer's 33rd Annual Meeting Trial results updated | Results | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2375545 |
| 06 Nov 2018 | Iovance Biotherapeutics reports third quarter 2018 financial results and provides corporate update | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2375637 |
| 29 Oct 2018 | Iovance Biotherapeutics to host Melanoma program update event for analysts and investors during SITC 2018 | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2373866 |
| 11 Oct 2018 | Iovance Biotherapeutics reports results from FDA end of phase 2 meeting and provides updates about the companys clinical program Result updated | Results | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2371343 |
| 06 Sep 2018 | The Rodman & Renshaw 20th Annual Global Investment Conference Study cohort II was expanded to 60 subjects. Subjects dosing commenced in EU in June 2018. | Enrollment Status | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk5NjIyfENoaWxkSUQ9NDExMTMwfFR5cGU9MQ==&t=1 |
| 06 Aug 2018 | Iovance Biotherapeutics reports second quarter 2018 financial results and provides corporate update | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2362261 |
| 28 Jun 2018 | Sarah Cannon Research Institute – UK Offers TIL Therapy to Patients with Metastatic Melanoma | Trial Update | http://www.businesswire.com/news/home/20180627006326/en/Sarah-Cannon-Research-Institute-%E2%80%93-UK-Offers |
| 07 Jun 2018 | Iovance Biotherapeutics Announces First Patient Dosed in Europe for | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol- |

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| | Ongoing C-144-01 Phase 2 Trials in Metastatic Melanoma First subject dosed in europe | | newsArticle&ID=2353696 |
| 10 May 2018 | Iovance Biotherapeutics Reports First Quarter 2018 Financial Results and Provides Corporate Update | Trial Update | http://globenewswire.com/news-release/2018/05/10/1500620/0/en/Iovance-Biotherapeutics-Reports-First-Quarter-2018-Financial-Results-and-Provides-Corporate-Update.html |
| 12 Mar 2018 | Iovance Biotherapeutics Reports Fourth Quarter and Full-Year 2017 Financial Results and Provides Corporate Update | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2337617 |
| 13 Dec 2017 | Iovance Biotherapeutics Announces Manufacturing Decision, Provides Clinical Updates and Highlights Pipeline Expansion at Analyst Day 2017 | Trial Update | http://globenewswire.com/news-release/2017/12/13/1261171/0/en/Iovance-Biotherapeutics-Announces-Manufacturing-Decision-Provides-Clinical-Updates-and-Highlights-Pipeline-Expansion-at-Analyst-Day-2017.html |
| 07 Dec 2017 | Novel cryopreserved tumor infiltrating lymphocytes (LN-144) administered to patients with metastatic melanoma demonstrates efficacy and tolerability in a multicenter Phase 2 clinical trial Trial results updated. | Results | https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-017-0297-3?site=jitc.biomedcentral.com |
| 31 Oct 2017 | Iovance Biotherapeutics Reports Third Quarter 2017 Financial Results | Trial Update | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2312953 |
| 31 Aug 2017 | Iovance Biotherapeutics Announces FDA Fast Track Designation for LN-144 for Treatment of Advanced Melanoma | Trial Update | http://ir.lbio.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2297863 |
| 01 Aug 2017 | Iovance Biotherapeutics Reports Second Quarter 2017 Financial Results | Trial Update | http://ir.lbio.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2290726 |
| 06 Jun 2017 | The Jefferies 2017 Global Healthcare Conference Results updatred | Results | http://wsw.com/webcast/jeff105/lbio/?lobby=true&day=1 |

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| 05 Jun 2017 | Lion Biotechnologies Announces Updated Data at 2017 American Society of Clinical Oncology Annual Meeting from Ongoing LN-144 Phase 2 Clinical Trial Result updated | Results | http://www.marketwired.com/press-release/lion-biotechnologies-announces-updated-data-2017-american-society-clinical-oncology-nasdaq-lbio-2220056.htm |
| 02 Jun 2017 | Efficacy of single administration of tumor-infiltrating lymphocytes (TIL) in heavily pretreated patients with metastatic melanoma following checkpoint therapy Trial results added. | Results | http://abstracts.asco.org/199/AbstView_199_185466.html |
| 19 May 2017 | Lion Biotechnologies Announces First Patient Dosed in Second Cohort of LN-144 Phase 2 Trial for Metastatic Melanoma First subject dosed in second cohort | Trial Update | http://www.lbio.com/news-media/press-releases/detail/97/lion-biotechnologies-announces-first-patient-dosed-in |
| 07 Mar 2017 | Lion Biotechnologies Reports Fourth Quarter and Full-Year 2016 Financial Results and Provides Corporate Update | Trial Update | http://www.lbio.com/news-media/press-releases/detail/90/lion-biotechnologies-reports-fourth-quarter-and-full-year |
| 04 Nov 2016 | Lion Biotechnologies Reports Third Quarter 2016 Financial Results and Provides Corporate Update | Trial Update | http://www.marketwired.com/press-release/lion-biotechnologies-reports-third-quarter-2016-financial-results-provides-corporate-2172855.htm |
| 08 Aug 2016 | Lion Biotechnologies Announces Second Quarter 2016 Financial Results | Trial Update | http://www.marketwired.com/press-release/lion-biotechnologies-announces-second-quarter-2016-financial-results-nasdaq-lbio-2148854.htm |
| 09 May 2016 | Lion Biotechnologies Announces First Quarter 2016 Financial Results | Trial Update | http://www.lbio.com/news-media/press-releases/detail/71/lion-biotechnologies-announces-first-quarter-2016-financial |
| 10 Mar 2016 | Lion Biotechnologies Announces 2015 Fourth-Quarter and Year-End Financial Results | Trial Update | http://www.marketwired.com/press-release/lion-biotechnologies-announces-2015-fourth-quarter-and- |

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| | | | year-end-financial-results-nasdaq-lbio-2104763.htm |
| 05 Nov 2015 | Lion Biotechnologies Announces Third Quarter 2015 Financial Results | Trial Update | http://lbio.com/press_releases/lion-biotechnologies-announces-third-quarter-2015-financial-results/ |
| 02 Nov 2015 | Lion Biotechnologies Announces the Departure of Dr. Laszlo Radvanyi | Trial Update | http://lbio.com/press_releases/lion-biotechnologies-announces-the-departure-of-dr-laszlo-radvanyi/ |
| 16 Sep 2015 | Lion Biotechnologies Announces Positive Updated Data From NCI's Phase 2 Study of TIL Therapy in the Treatment of Metastatic Melanoma | Trial Update | http://globenewswire.com/news-release/2015/09/16/768774/10149582/en/Lion-Biotechnologies-Announces-Positive-Updated-Data-From-NCI-s-Phase-2-Study-of-TIL-Therapy-in-the-Treatment-of-Metastatic-Melanoma.html |
| 14 Sep 2015 | Lion Biotechnologies Opens Enrollment in Phase 2 Study of LN-144 for the Treatment of Refractory Metastatic Melanoma | Trial Initiation;Trial Status;Trial Update | http://lbio.com/press_releases/lion-biotechnologies-opens-enrollment-in-phase-2-study-of-ln-144-for-the-treatment-of-refractory-metastatic-melanoma/ |
| 10 Jun 2015 | Lion Biotechnologies Receives Orphan Drug Designation for LN-144 for the Treatment of Malignant Melanoma | Trial Update | http://globenewswire.com/news-release/2015/06/10/743652/10138048/en/Lion-Biotechnologies-Receives-Orphan-Drug-Designation-for-LN-144-for-the-Treatment-of-Malignant-Melanoma.html |
| 15 Dec 2014 | Lion Biotechnologies Names Elma Hawkins President, Chief Executive Officer and Director | Trial Update | http://globenewswire.com/news-release/2014/12/15/691215/10112300/en/Lion-Biotechnologies-Names-Elma-Hawkins-President-Chief-Executive-Officer-and-Director.html |

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| 20 Aug 2014 | Lion Biotechnologies Names Elma Hawkins President and Chief Operating Officer | Trial Update | http://lbio.com/press_releases/lion-biotechnologies-names-elma-hawkins-president-and-chief-operating-officer/ |
| | GlobalData Primary Research from Insights Results updated | Results | |

**Insights (9)**

| Published Date | Headline |
|---|---|
| 29-Jun-2017 | Iovance's early Phase II C-144-01 melanoma data promising for further results but small population draws pause to data strength – experts |
| 29-Jun-2017 | Iovance's C-144-01 for melanoma may need more subjects for stronger FDA approval prospects; unclear placement in treatment schedule if approved – experts |
| 11-Jul-2017 | Iovance collaborates with CRO PRA Health Sciences for Phase II C-144-01 melanoma trial, 18 subjects enrolled at one site – source |
| 11-Oct-2017 | November 2017 Catalyst Monitor Tracks 17 Key Events |
| 20-Jul-2018 | Iovance's Phase II TIL therapy for HNSCC, cervical cancer triggers expert reactions ranging from poor to cautiously optimistic |
| 24-Jul-2018 | Iovance's tumor-infiltrating lymphocyte therapy not yet deemed clearly safer than CAR-Ts; CRS management experience assuages safety concerns, experts say |
| 09-Jan-2020 | Iovance's TIL therapy adoption will involve logistical learning curve, but durable responses could increase uptake attractiveness, experts say |
| 20-Jul-2020 | Replimune's Phase II oncolytic cancer agent is likely to have a higher efficacy hurdle for cSCC due to wide utility of Regeneron's Libtayo, experts say |
| 21-Dec-2023 | Iovance's Lifileucel Has Boosted FDA Approval Chances in Metastatic Melanoma but May Struggle to Find Fit Enough Patients in Clinic |

**History of changes**

| Modified Date | Update Type | Description | From Data | To Data | Source Date | Source Type | Source |
|---|---|---|---|---|---|---|---|
| 23-Feb-2024 | Trial Date | Trial Estimated End Date Added **"15 Jan 2025"** | N/A | 15 Jan 2025 | | | |
| 20-Feb- | Trial | Trial | N/A | 26 May | 26-May- | Company | https://ir.iovance. |

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|---|---|---|---|---|---|---|---|
| 2024 | Date | Actual End Date Added **"26 May 2022"** | | 2022 | 2022 | Press Release | com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data |
| 20-Feb-2024 | Trial Contacts | Trial Contacts Updated | | | | | |
| 20-Feb-2024 | Study Design/ Trial Description | Trial Description Updated | | | 16-Feb-2024 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovances-amtagvitm-lifileucel-receives-us-fda-accelerated |
| 20-Feb-2024 | Trial Result | Trial Conclusion Updated | | | 16-Feb-2024 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovances-amtagvitm-lifileucel-receives-us-fda-accelerated |
| 20-Feb-2024 | Trial Result | Trial Results Updated | | | 16-Feb-2024 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovances-amtagvitm-lifileucel-receives-us-fda-accelerated |
| 15-Feb-2024 | Study Design/ Trial Description | Trial Description Updated | | | 06-Feb-2024 | Clinical Trial Registry | https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/study/39231 |
| 15-Feb-2024 | Study Design/ Trial Description | Virtual Component Added | N/A | Telemedicine | 06-Feb-2024 | Clinical Trial Registry | https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/study/39231 |
| 15-Feb-2024 | Study Design/ Trial Description | Trial Description Updated | | | 06-Feb-2024 | Clinical Trial Registry | https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/study/39231 |

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| 06-Feb-2024 | Trial Result | Trial Results Updated | | | 06-Dec-2023 | Conferences | https://cslide.ctimeetingtech.com/immuno23hybrid/attendee/confcal/show/session/10 |
| 29-Dec-2023 | Acronym/Secondary ID | Trial Secondary ID Updated | 18309, 2017-000760-15, 2017-02031, C-144-01, CDR769149, EudraCT-2017-000760-15, GDC40003238, GDCT0231030, NCI-2015-01957, P 54117, S16-00804, UKCTG-39529 | 18309, 2017-000760-15, 2017-000760-15-GB, 2017-02031, BASEC 2017-02031, C-144-01, CDR769149, EUCTR2017-000760-15, EudraCT-2017-000760-15, GDC40003238, GDCT0231030, NCI-2015-01957, P 54117, S16-00804, SNCTP000002819, UKCTG- | 23-Dec-2023 | Clinical Trial Registry | https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/study/39231 |

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| | | | | 39529 | | | |
| 28-Nov-2023 | Study Design/ Trial Description | Trial Description Updated | | | 01-Nov-2023 | Conferences | https://jitc.bmj.com/content/11/Suppl_1/A873 |
| 28-Nov-2023 | Trial Result | Trial Results Updated | | | 01-Nov-2023 | Conferences | https://jitc.bmj.com/content/11/Suppl_1/A873 |
| 28-Nov-2023 | Trial Result | Trial Results Updated | | | 01-Nov-2023 | Conferences | https://jitc.bmj.com/content/11/Suppl_1/A873 |
| 28-Nov-2023 | Enrollment | Number of Subjects Analyzed Updated to **"181"** | N/A | 181 | 01-Nov-2023 | Conferences | https://jitc.bmj.com/content/11/Suppl_1/A873 |
| 23-Nov-2023 | Study Design/ Trial Description | Trial Description Updated | | | 20-Oct-2023 | Conferences | https://cslide.ctimeetingtech.com/esmo2023/attendee/confcal/presentation/list?q=1086MO&r=st%7E9 |
| 23-Nov-2023 | Trial Result | Trial Conclusion Updated | | | 20-Oct-2023 | Conferences | https://cslide.ctimeetingtech.com/esmo2023/attendee/confcal/presentation/list?q=1086MO&r=st%7E9 |
| 23-Nov-2023 | Trial Result | Trial Results Updated | | | 20-Oct-2023 | Conferences | https://cslide.ctimeetingtech.com/esmo2023/attendee/confcal/presentation/list?q=1086MO&r=st%7E9 |
| 21-Nov-2023 | Trial Result | Trial Results Updated | | | 16-Nov-2023 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-clinical-data-lifileucel-1 |
| 21-Nov-2023 | Trial Result | Trial Conclusion Updated | | | 16-Oct-2023 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics- |

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| | | | | | | | announces-clinical-data-lifileucel-1 |
| 14-Aug-2023 | Study Design/ Trial Description | Trial Notes Updated | | | 08-Aug-2023 | Company Presentation | https://ir.iovance.com/node/13881/pdf |
| 17-Jul-2023 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 13-Jul-2023 | Trial Date | Trial Estimated End Date Removed | 01 Jul 2021 | N/A | 12-Jul-2023 | Clinical Trial Registry | https://classic.clinicaltrials.gov/ct2/history/NCT02360579?A=62&B=63&C=Side-by-Side#StudyPageTop |
| 13-Jul-2023 | Primary/ Secondary outcomes | Primary Outcome Measures Updated | | | 12-Jul-2023 | Clinical Trial Registry | https://classic.clinicaltrials.gov/ct2/history/NCT02360579?A=62&B=63&C=Side-by-Side#StudyPageTop |
| 13-Jul-2023 | Primary/ Secondary outcomes | Secondary Outcome Measures Updated | | | 12-Jul-2023 | Clinical Trial Registry | https://classic.clinicaltrials.gov/ct2/history/NCT02360579?A=62&B=63&C=Side-by-Side#StudyPageTop |
| 15-Jun-2023 | Primary/ Secondary outcomes | Secondary Outcome Measures Updated | | | 08-Jun-2023 | Company Presentation | https://ir.iovance.com/static-files/f7e39cfa-9298-4657-86e6-41aca977f813 |
| 02-May-2023 | Trial Result | Trial Results Updated | | | 23-Apr-2023 | Conferences | https://ebmt2023.abstractserver.com/program/#/details/presentations/963 |
| 30-Mar-2023 | Trial Result | Trial Results Updated | | | 25-Mar-2023 | Conferences | https://link.springer.com/content/pdf/10.1245/s10434-023-13332-7.pdf?pdf=inline%20link (Abstract: 64 |
| 22-Feb- | Primary/ | Secondary | | | 15-Feb- | Conference | https://astct-29- |

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| 2023 | Secondary outcomes | Outcome Measures Updated | | | 2023 | s | s2.elsevierdigitaledition.com/ |
| 22-Feb-2023 | Subjects | Trial Subjects Updated | Asymptomatic, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status | Asymptomatic, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status | 15-Feb-2023 | Conferences | https://astct-29-s2.elsevierdigitaledition.com/ |
| 22-Feb-2023 | Subjects | Trial Subjects Updated | Asymptomatic, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status | Asymptomatic, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status | 15-Feb-2023 | Conferences | https://astct-29-s2.elsevierdigitaledition.com/ |
| 22-Feb-2023 | Trial Result | Post-hoc Results Updated | | | 15-Feb-2023 | Conferences | https://astct-29-s2.elsevierdigitaledition.com/ |
| 22-Feb-2023 | Trial Result | Trial Conclusion Updated | | | 15-Feb-2023 | Conferences | https://astct-29-s2.elsevierdigitaledition.com/ |

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| 08-Feb-2023 | Trial Result | Trial Results Updated | | | 08-Dec-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-immuno-oncology-congress/number-of-il-2-doses-and-clinical-outcomes-of-tumor-infiltrating-lymphocyte-til-cell-therapy-post-hoc-analysis-of-the-c-144-01-trial-of-lifileuc |
| 27-Jan-2023 | Subjects | Inclusion Criteria Updated | | | 11-Jan-2023 | Conferences | https://jpmorgan.metameetings.net/events/healthcare23/sessions/43800/webcast?gpu_only=true&kiosk=true (Slide 13) |
| 03-Jan-2023 | Primary/ Secondary outcomes | Primary Outcome Measures Updated | | | 10-Sep-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano; https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdf |
| 03-Jan-2023 | Study Design/ Trial Description | Trial Description Updated | | | 10-Sep-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano; https://www.iovance.com/uploads/ |

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| | | | | | | | Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdf |
| 03-Jan-2023 | Subjects | Exclusion Criteria Updated | | | 10-Sep-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano; https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdf |
| 03-Jan-2023 | Subjects | Inclusion Criteria Updated | | | 10-Sep-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano; https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdf |
| 03-Jan-2023 | Subjects | Trial Subjects Updated | Asymptomatic, Eastern Cooperative Oncology Group | Asymptomatic, Eastern Cooperative Oncology Group | 10-Sep-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til- |

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| | | | (ECOG or WHO or Zubrod) Performance Status | (ECOG or WHO or Zubrod) Performance Status | | | cell-therapy-in-patients-with-advanced-melano; https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdf |
| 03-Jan-2023 | Enrollment | Number of Subjects Enrolled Changed from **"178"** to **"181"** | 178 | 181 | | | |
| 28-Dec-2022 | Study Design/ Trial Description | Trial Description Updated | | | 21-Dec-2022 | Company Presentation | https://ir.iovance.com/static-files/819a66e9-aa58-40d3-9d6d-35dc4e55e98c |
| 28-Dec-2022 | Study Design/ Trial Description | Study Design Updated | Nonrandomized, Uncontrolled, Parallel Assignment, Open-label, Cohort, Treatment, Prospective, Multi-centered, Pivotal/ Registration, Global Trial | Nonrandomized, Uncontrolled, Parallel Assignment, Single Group Assignment, Open-label, Cohort, Treatment, Prospective, Multi-centered, Pivotal/ | | | |

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| | | | | Registration, Global Trial | | | |
| 23-Nov-2022 | Trial Result | Trial Results Updated | | | 10-Nov-2022 | Company Presentation | https://ir.iovance.com/static-files/b668e3af-7748-41d2-9b58-29108038a59c |
| 22-Nov-2022 | Primary/ Secondary outcomes | Primary Outcome Measures Updated | | | 08-Nov-2022 | Conferences | https://jitc.bmj.com/content/10/Suppl_2/A821 |
| 22-Nov-2022 | Study Design/ Trial Description | Trial Description Updated | | | 08-Nov-2022 | Conferences | https://jitc.bmj.com/content/10/Suppl_2/A821 |
| 22-Nov-2022 | Subjects | Exclusion Criteria Updated | | | 08-Nov-2022 | Conferences | https://jitc.bmj.com/content/10/Suppl_2/A821 |
| 22-Nov-2022 | Subjects | Inclusion Criteria Updated | | | 08-Nov-2022 | Conferences | https://jitc.bmj.com/content/10/Suppl_2/A821; https://www.iovance.com/uploads/Sarnaik_SITC2022_24-oral-presentation_FINAL-compressed-2426-publication.pdf |
| 22-Nov-2022 | Trial Result | Trial Results Updated | | | 08-Nov-2022 | Conferences | https://jitc.bmj.com/content/10/Suppl_2/A821; https://www.iovance.com/uploads/Sarnaik_SITC2022_24-oral-presentation_FINAL-compressed-2426-publication.pdf |
| 10-Nov-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 30-Sep-2022 | Company SEC Filings | https://www.sec.gov/ix?doc=%2Farchives%2Fedgar%2Fdata%2F1425205%2F000155837022016295%2Fiova-20220930x10q.htm |

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| 18-Oct-2022 | Acronym/Secondary ID | Trial Secondary ID Updated | 18309, 2017-000760-15, C-144-01, CDR769149, EudraCT-2017-000760-15, GDC40003238, GDCT0231030, NCI-2015-01957, P 54117, S16-00804, UKCTG-39529 | 18309, 2017-000760-15, 2017-02031, C-144-01, CDR769149, EudraCT-2017-000760-15, GDC40003238, GDCT0231030, NCI-2015-01957, P 54117, S16-00804, UKCTG-39529 | | | |
| 13-Sep-2022 | Trial Result | Trial Results Updated | | | 10-Sep-2022 | Conferences | https://oncologypro.esmo.org/meeting-resources/esmo-congress/efficacy-and-safety-of-lifileucel-an-investigational-autologous-tumor-infiltrating-lymphocyte-til-cell-therapy-in-patients-with-advanced-melano; https://www.iovance.com/uploads/Larkin_Anti-LAG3_ESMO-2022_FINAL_2022-08-31-for-website-2401-publication.pdf |

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| 29-Aug-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 25-Aug-2022 | Company Press Release | https://www.globenewswire.com/news-release/2022/08/25/2504495/0/en/Iovance-Biotherapeutics-Initiates-Biologics-License-Application-BLA-Submission-for-Lifileucel-in-Advanced-Melanoma.html |
| 15-Jul-2022 | Biomarkers | Biomarkers Updated | Aspartate Aminotransferase, Unspecified; B-Raf proto-oncogene, serine/threonine kinase; Bilirubin; BRAF p.Val600; C-X-C motif chemokine ligand 10; CD274 Molecule; Leukocytes; Lymphocytes; Neutrophils; Platelet | Aspartate Aminotransferase, Unspecified; B-Raf proto-oncogene, serine/threonine kinase; Bilirubin; BRAF p.Val600; C-X-C motif chemokine ligand 10; CD274 Molecule; Leukocytes; Lymphocytes; Neutrophils; Platelet | 15-Jul-2022 | Journals | https://meetings.asco.org/abstracts-presentations/210188 |

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| | | | s | s; Tumor Mutation Burden | | | |
| 15-Jul-2022 | Biomarkers | Biomarkers Updated | Aspartate Aminotransferase, Unspecified; B-Raf proto-oncogene, serine/threonine kinase; Bilirubin; BRAF p.Val600; C-X-C motif chemokine ligand 10; CD274 Molecule; Leukocytes; Lymphocytes; Neutrophils; Platelets; Tumor Mutation Burden | Aspartate Aminotransferase, Unspecified; B-Raf proto-oncogene, serine/threonine kinase; Bilirubin; BRAF p.Val600; C-X-C motif chemokine ligand 10; CD274 Molecule; L-Lactate Dehydrogenase; Leukocytes; Lymphocytes; Neutrophils; Platelets; | 15-Jul-2022 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data |

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| | | | | Tumor Mutation Burden | | | |
| 11-Jul-2022 | Study Design/ Trial Description | Trial Description Updated | | | 29-Jun-2022 | Company Presentation | https://ir.iovance.com/static-files/8e1e997d-4d25-47cd-a735-fc8977cfcc60 |
| 01-Jul-2022 | Trial Result | Pooled Results Updated | | | 06-Jun-2022 | Conferences | https://meetings.asco.org/abstracts-presentations/210188 |
| 20-Jun-2022 | Trial Result | Top-line Results Updated | | | 09-Jun-2022 | Conferences | https://wsw.com/webcast/jeff240/iova/1845375 |
| 06-Jun-2022 | End point Status | Endpoint Status Updated to **"Achieved"** | N/A | Achieved | | | |
| 06-Jun-2022 | Trial Result | Trial Conclusion Updated | | | | | |
| 02-Jun-2022 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 02-Jun-2022 | Trial Status | Trial Status Changed from **"Ongoing, not recruiting"** to **"Completed"** | Ongoing, not recruiting | Completed | 26-May-2022 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data |
| 30-May-2022 | Trial Result | Trial Results Updated | | | 26-May-2022 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovance- |

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| | | | | | | | biotherapeutics-announces-positive-clinical-data |
| 30-May-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 26-May-2022 | Company Press Release | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-positive-clinical-data |
| 18-May-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 01-May-2022 | Company Presentation | https://ir.iovance.com/static-files/1fd55821-d1ee-4403-8aa5-7f25f83894b1 |
| 05-May-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 26-Apr-2022 | Conferences | https://wsw.com/webcast/chard11/iova/1911420 |
| 25-Mar-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 01-Mar-2022 | Company Presentation | https://ir.iovance.com/static-files/efb8f5d3-1eb0-4bc0-baf7-8ff5c54e6dbd |
| 10-Feb-2022 | Study Design/ Trial Description | Trial Notes Updated | | | 12-Jan-2022 | Conferences | https://ir.iovance.com/static-files/3f991737-1354-441b-9ba2-e4231f1fb3d5 (Slide 27) |
| 10-Feb-2022 | Trial Result | Trial Results Updated | | | 12-Jan-2022 | Conferences | https://ir.iovance.com/static-files/3f991737-1354-441b-9ba2-e4231f1fb3d5 (slide 12) |
| 08-Jun-2021 | Trial Result | Trial Results Updated | | | | | https://meetinglibrary.asco.org/record/196423/abstract |
| 08-Jun-2021 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/static-files/7f1edb46-6a77-4e34-b907-6402f4b5355f |
| 08-Jun- | Trial | Trial | | | | | https://www.globenewswire.com/n |

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| 2021 | Result | Results Updated | | | | | ews-release/2021/06/06/2242393/0/en/Iovance-Biotherapeutics-Announces-33-Month-Follow-Up-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html |
| 28-May-2021 | Study Design/ Trial Description | Trial Notes Updated | | | | | https://www.globenewswire.com/news-release/2021/05/06/2224972/0/en/Iovance-Biotherapeutics-Reports-First-Quarter-2021-Financial-Results-and-Corporate-Updates.html |
| 21-May-2021 | Trial Date | Trial Actual Start Date Changed from **"01 Apr 2017"** to **"14 Sep 2015"** | 01 Apr 2017 | 14 Sep 2015 | | | https://ir.iovance.com/news-releases/news-release-details/lion-biotechnologies-opens-enrollment-phase-2-study-ln-144 |
| 18-May-2021 | Trial Date | Trial Actual Start Date Changed from **"14 Sep 2015"** to **"01 Apr 2017"** | 14 Sep 2015 | 01 Apr 2017 | | | https://ascopubs.org/doi/full/10.1200/JCO.21.00612 |
| 18-May-2021 | Trial Result | Trial Results Updated | | | | | https://ascopubs.org/doi/full/10.1200/JCO.21.00612 |
| 05-May-2021 | Study Design/ Trial Descripti | Trial Notes Updated | | | | | https://www.globenewswire.com/news-release/2021/04/28/2218849/0/en/Iovance- |

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| | on | | | | | | Biotherapeutics-to-Present-Clinical-Data-for-Lifileucel-in-Advanced-Melanoma-at-ASCO-2021-Annual-Meeting.html |
| 15-Apr-2021 | Trial Result | Trial Results Updated | | | | | https://www.abstractsonline.com/pp8/#!/9325/presentation/5139; https://www.iovance.com/wp-content/uploads/AACR21_C-144-01_Long-Term-Follow-Up_Chesney_CT008_FINAL_updated_11APR2021.pdf |
| 15-Apr-2021 | Trial Result | Trial Results Updated | | | | | |
| 26-Mar-2021 | Trial Date | Trial Estimated End Date Changed from **"01 Jul 2020"** to **"01 Jul 2021"** | 01 Jul 2020 | 01 Jul 2021 | | | https://clinicaltrials.gov/ct2/history/NCT02360579?A=61&B=62&C=Side-by-Side#StudyPageTop |
| 16-Mar-2021 | Study Design/ Trial Description | Trial Description Updated | | | | | https://journey.ct.events/view/e8ba4dfc-f963-4055-b1f3-18289dd9b82e |
| 09-Mar-2021 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-2 |
| 09-Mar-2021 | Study Design/ Trial Description | Trial Description Updated | | | | | |

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| 05-Feb-2021 | Trial Result | Trial Results Updated | | | | | https://jpmorgan.metameetings.net/events/healthcare21/sessions/35760-iovance-biotherapeutics-inc/webcast?gpu_only=true&kiosk=true (Slides 05,16,17,18,19,20,21,22) |
| 08-Oct-2020 | Study Design/ Trial Description | Trial Description Updated | | | | | https://ir.iovance.com/static-files/14662ea1-537d-4967-a558-94ae63ec1154 |
| 08-Oct-2020 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/static-files/14662ea1-537d-4967-a558-94ae63ec1154 |
| 06-Oct-2020 | Study Design/ Trial Description | Trial Description Updated | | | | | https://www.globenewswire.com/news-release/2020/10/05/2103814/0/en/Iovance-Biotherapeutics-Provides-Update-for-Lifileucel-in-Metastatic-Melanoma.html#:~:text=Iovance%20Biotherapeutics%20Provides%20Update%20for%20Lifileucel%20in%20Metastatic%20Melanoma,-Email%20Print%20Friendly&text=October%2005%2C%202020%2016%3A01,Source%3A%20Iovance%20Biotherapeutics%2C%20Inc.&text=The%20Company%20believes%20that%20clinical,a%20treatment%20for%20metastatic%20melanoma. |
| 27-Aug-2020 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/static-files/dd026048-1c0a-42ff-bf4d-bec7f9acbd98 |

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| 21-Jul-2020 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 17-Jun-2020 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/static-files/bb47a08e-7d8f-44e4-9b81-a5173a564984 |
| 01-Jun-2020 | Trial Result | Trial Conclusion Updated | | | | | |
| 01-Jun-2020 | Trial Result | Trial Results Updated | | | | | |
| 01-Jun-2020 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 01-Jun-2020 | Study Design/ Trial Description | Study Design Updated | | | | | |
| 01-Jun-2020 | Subjects | Trial Subjects Updated | | | | | |
| 29-May-2020 | Study Design/ Trial Description | Trial Notes Updated | | | | | https://www.globenewswire.com/news-release/2020/05/27/2039716/0/en/Iovance-Reports-Pivotal-Cohort-4-Data-for-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Lifileucel-from-C-144-01-Clinical-Study-in-Advanced-Melanoma.html |
| 29-May-2020 | Trial Result | Trial Results Updated | | | | | https://www.globenewswire.com/news-release/2020/05/ |

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| | | | | | | | 27/2039716/0/en/Iovance-Reports-Pivotal-Cohort-4-Data-for-Tumor-Infiltrating-Lymphocyte-TIL-Therapy-Lifileucel-from-C-144-01-Clinical-Study-in-Advanced-Melanoma.html |
| 01-May-2020 | Study Design/ Trial Description | Trial Notes Updated | | | | | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-present-updated-data-clinical-study |
| 08-Apr-2020 | Trial Locations | Trial Locations Updated | | | | | |
| 16-Mar-2020 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/static-files/29193916-3d6b-413b-b450-698af14a0a58 |
| 05-Mar-2020 | Trial Result | Trial Conclusion Updated | | | | | |
| 05-Mar-2020 | Trial Date | Trial Actual End Date Updated | | | | | |
| 05-Mar-2020 | Trial Status | Trial Status Changed from **"Completed"** to **"Ongoing, not recruiting"** | Completed | Ongoing, not recruiting | | | |
| 04-Mar-2020 | Study Design/ Trial Descripti | Trial Notes Updated | | | | | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics- |

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| | on | | | | | | reports-fourth-quarter-and-full-year-1 |
| 04-Mar-2020 | Trial Date | Trial Actual End Date Updated | | | | | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-1 |
| 04-Mar-2020 | Trial Status | Trial Status Changed from **"Ongoing, not recruiting"** to **"Completed"** | Ongoing, not recruiting | Completed | | | https://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-fourth-quarter-and-full-year-1 |
| 04-Mar-2020 | Trial Result | Trial Conclusion Updated | | | | | |
| 04-Mar-2020 | Subjects | Trial Subjects Updated | | | | | |
| 07-Feb-2020 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 07-Feb-2020 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 06-Feb-2020 | Primary/ Secondary outcomes | Secondary Outcome Measure Updated | | | | | https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f |
| 06-Feb-2020 | Study Design/ | Trial Descriptio | | | | | https://ir.iovance.com/static-files/e02bf2dc- |

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| | Trial Description | n Updated | | | | | 235a-42ca-ae14-2f2912da789f |
| 06-Feb-2020 | Study Design/ Trial Description | Trial Notes Updated | | | | | https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f |
| 06-Feb-2020 | Trial Result | Trial Results Updated | | | | | https://ir.iovance.com/static-files/e02bf2dc-235a-42ca-ae14-2f2912da789f |
| 06-Feb-2020 | Trial Result | Trial Results Updated | | | | | |
| 24-Jan-2020 | Trial Locations | Trial Locations Updated | | | | | |
| 22-Jan-2020 | Enrollment | Number of Subjects Enrolled Changed from "N/A" to "178" | N/A | 178 | | | https://clinicaltrials.gov/ct2/history/NCT02360579?A=60&B=61&C=Side-by-Side#StudyPageTop |
| 22-Jan-2020 | Study Design/ Trial Description | Trial Description Updated | | | | | https://clinicaltrials.gov/ct2/history/NCT02360579?A=60&B=61&C=Side-by-Side#StudyPageTop |
| 22-Jan-2020 | Trial Date | Trial Estimated End Date Changed from **"01 Mar 2020"** to **"01 Jul 2020"** | 01 Mar 2020 | 01 Jul 2020 | | | https://clinicaltrials.gov/ct2/history/NCT02360579?A=60&B=61&C=Side-by-Side#StudyPageTop |
| 17-Jan-2020 | Trial Status | Trial Status Changed | Ongoing, recruiti | Ongoing, not recruiti | | | https://www.globenewswire.com/news-release/2020/01/15/1970831/0/en |

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| | | from **"Ongoing, recruiting"** to **"Ongoing, not recruiting"** | ng | ng | | | /Iovance-Biotherapeutics-Completes-Patient-Dosing-in-Registration-Enabling-Cohort-4-of-the-C-144-01-Melanoma-Study-with-Lifileucel.html |
| 10-Jan-2020 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 07-Jan-2020 | Trial Locations | Trial Locations Updated | | | | | |
| 07-Jan-2020 | Trial Locations | Trial Locations Updated | | | | | |
| 27-Dec-2019 | Trial Locations | Trial Locations Updated | | | | | https://clinicaltrials.gov/ct2/history/NCT02360579?A=59&B=60&C=Side-by-Side#StudyPageTop |
| 23-Dec-2019 | Study Design/ Trial Description | Trial Description Updated | | | | | https://registration.sitesolutionsworldwide.com/synergy/v_1_/event_files/Late_Breaking_Abstracts_2019.pdf |
| 23-Dec-2019 | Trial Result | Trial Results Updated | | | | | https://registration.sitesolutionsworldwide.com/synergy/v_1_/event_files/Late_Breaking_Abstracts_2019.pdf |
| 02-Dec-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 28-Nov-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | ir.iovance.com/static-files/b61c8cbf-390b-42fc-accf-aa67941cd068 |

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| 28-Nov-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 27-Nov-2019 | Trial Locations | Trial Locations Updated | | | | | https://clinicaltrials.gov/ct2/history/NCT02360579?A=58&B=59&C=Side-by-Side#StudyPageTop |
| 25-Nov-2019 | Subjects | Trial Subjects Updated | | | | | http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-results-subgroup-analysis |
| 25-Nov-2019 | Trial Result | Trial Results Updated | | | | | http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-announces-results-subgroup-analysis |
| 20-Nov-2019 | Study Design/ Trial Description | Trial Description Updated | | | | | http://ir.iovance.com/static-files/1b1e5731-fa4e-4341-8454-eec6e83ff2c |
| 20-Nov-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/static-files/1b1e5731-fa4e-4341-8454-eec6e83ff2c |
| 20-Nov-2019 | Trial Result | Trial Results Updated | | | | | http://ir.iovance.com/static-files/1b1e5731-fa4e-4341-8454-eec6e83ff2c |
| 12-Nov-2019 | Trial Result | Trial Results Updated | | | | | https://www.globenewswire.com/news-release/2019/11/08/1943947/0/en/Iovance-Biotherapeutics-Announces-Updated-Phase-2- |

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| | | | | | | | Clinical-Data-from-the-Lifileucel-Metastatic-Melanoma-Trial-at-the-Society-for-Immunotherapy-of-Cancer-34th-Annual-Meeting.html |
| 11-Nov-2019 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | https://www.iovance.com/clinical/c-144-01-metastatic-melanoma/ |
| 07-Nov-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/news-releases/news-release-details/iovance-biotherapeutics-reports-third-quarter-and-september-year |
| 01-Nov-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/static-files/47dfc7e0-e16f-4332-b24e-72e53e59c702 |
| 01-Nov-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/static-files/f31d23c0-b015-4ac4-a2bc-5b41dbadfdf5 |
| 31-Oct-2019 | Sponsor/ Collaborator/CRO | Trial CRO Updated | | | | | |
| 17-Oct-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 23-Sep-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 17-Sep-2019 | Trial Locations | Trial Locations Updated | | | | | |

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|---|---|---|---|---|---|---|---|
| 29-Jul-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 18-Jul-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/static-files/885a2bb7-8102-4b2c-95d1-e905679b2845 |
| 16-Jul-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/static-files/633da1e2-5d44-4513-8223-75317481f580 |
| 16-Jul-2019 | Sponsor/ Collaborator/CRO | Trial CRO Updated | | | | | |
| 27-Jun-2019 | Trial Result | Trial Results Updated | | | | | www.wsw.com/webcast/jeff118/iova/?lobby=true&day=2 |
| 24-Jun-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 19-Jun-2019 | Trial Result | Trial Results Updated | | | | | http://abstracts.asco.org/239/AbstView_239_266867.html |
| 14-Jun-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 12-Jun-2019 | Trial Contacts | Trial Contacts Updated | | | | | |
| 12-Jun-2019 | Trial Contacts | Trial Contacts Updated | | | | | |
| 07-Jun-2019 | Trial Result | Trial Results Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA3MTc0fENoaWxkSUQ9NDIwMDA3fFR5cGU9MQ==&t=1 |

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|---|---|---|---|---|---|---|---|
| 04-Jun-2019 | Trial Result | Trial Results Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2400232 |
| 22-May-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA2ODY4fENoaWxkSUQ9NDE5NjA4fFR5cGU9MQ==&t=1 |
| 17-May-2019 | Trial Result | Trial Results Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2398790 |
| 12-Apr-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA1NDUzfENoaWxkSUQ9NDE3ODczfFR5cGU9MQ==&t=1 |
| 09-Apr-2019 | Trial Result | Trial Results Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2392939 |
| 09-Apr-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 05-Apr-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 04-Apr-2019 | Acronym/Secondary ID | Trial Acronym Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2393137 |
| 02-Apr-2019 | Trial Result | Trial Results Updated | | | | | https://www.abstractsonline.com/pp8/#!/6812/presentation/9204 |
| 29-Mar-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 22-Mar-2019 | Trial Locations | Trial Locations Updated | | | | | |

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|---|---|---|---|---|---|---|---|
| 21-Mar-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzA1MTUwfENoaWxkSUQ9NDE3NDkyfFR5cGU9MQ==&t=1 |
| 08-Mar-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 07-Mar-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 04-Mar-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | services.corporate-ir.net/SEC/Document.Service?id=P3VybD1hSFIwY0RvdkwyRndhUzUwWlc1cmQybDZZWEprTG1OdmJTOWtiM2R1Ykc5aFpDNXdhSEEvWVdOMGFXOXVQVkJFUmlacGNHRm5aVDB4TWpjME1UYzJOU1p6ZFdKemFXUTlOVGM9JnR5cGU9MiZmbj1Jb3ZhbmNlQmlvdGhlcmFwZXV0aWNzSW5jLnBkZg== |
| 04-Mar-2019 | Trial Result | Trial Results Updated | | | | | https://meetinglibrary.asco.org/record/170363/abstract |
| 21-Feb-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAzOTUzfENoaWxkSUQ9NDE2MTI1fFR5cGU9MQ==&t=1 |
| 18-Feb-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 08-Feb-2019 | Trial Locations | Trial Locations Updated | | | | | |
| 07-Feb-2019 | Trial Status | Trial Status Changed | Ongoing, not recruiti | Ongoing, recruiti | | | |

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|---|---|---|---|---|---|---|---|
| | | from **"Ongoing, not recruiting** " to **"Ongoing, recruiting** " | ng | ng | | | |
| 07-Feb-2019 | Trial Contacts | Trial Contacts Updated | | | | | |
| 24-Jan-2019 | Study Design/ Trial Description | Trial Description Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1(Slide 19) |
| 24-Jan-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1(Slide 04) |
| 24-Jan-2019 | Trial Result | Trial Results Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyOTg1fENoaWxkSUQ9NDE1MDA4fFR5cGU9MQ==&t=1(Slide 04) |
| 23-Jan-2019 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 23-Jan-2019 | Study Design/ Trial Description | Study Design Updated | | | | | |
| 11-Jan-2019 | Trial Date | Trial Estimated | 01 Mar 2019 | 01 Mar 2020 | | | |

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|---|---|---|---|---|---|---|---|
| | | End Date Changed from **"01 Mar 2019"** to **"01 Mar 2020"** | | | | | |
| 11-Jan-2019 | Subjects | Exclusion Criteria Updated | | | | | |
| 11-Jan-2019 | Subjects | Inclusion Criteria Updated | | | | | |
| 11-Jan-2019 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 07-Jan-2019 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | |
| 07-Jan-2019 | Primary/ Secondary outcomes | Secondary Outcome Measure Updated | | | | | |
| 07-Jan-2019 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 07-Jan-2019 | Subjects | Exclusion Criteria Updated | | | | | |
| 07-Jan-2019 | Subjects | Inclusion Criteria Updated | | | | | |
| 07-Jan-2019 | Enrollment | Number of Subjects | 100 | 164 | | | |

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|---|---|---|---|---|---|---|---|
| | | Planned Changed from "100" to "164" | | | | | |
| 12-Dec-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAyNjIyfENoaWxkSUQ9NDE0NTY5fFR5cGU9MQ==&t=1 |
| 30-Nov-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 29-Nov-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 29-Nov-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 28-Nov-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 27-Nov-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 16-Nov-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAxNzc0fENoaWxkSUQ9NDEzNTM2fFR5cGU9MQ==&t=1 |
| 16-Nov-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAxNzc0fENoaWxkSUQ9NDEzNTM2fFR5cGU9MQ==&t=1 |
| 16-Nov-2018 | Trial Result | Trial Results Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAxNzc0fENoaWxkSUQ9NDEzNTM2fFR5cGU9MQ==&t=1 |
| 08-Nov- | Trial | Trial | | | | | http://ir.iovance.c |

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| 2018 | Result | Results Updated | | | | | om/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2375545 |
| 08-Nov-2018 | Trial Result | Trial Results Updated | | | | | https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-018-0423-x |
| 08-Nov-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 31-Oct-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 30-Oct-2018 | Trial Status | Trial Status Changed from **"Ongoing, recruiting"** to **"Ongoing, not recruiting"** | Ongoing, recruiting | Ongoing, not recruiting | | | |
| 30-Oct-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 22-Oct-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 22-Oct-2018 | Trial Result | Trial Results Updated | | | | | |
| 15-Oct-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2371343 |

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|---|---|---|---|---|---|---|---|
| 15-Oct-2018 | Trial Result | Trial Results Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2371343 |
| 08-Oct-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NzAwMjU4fENoaWxkSUQ9NDExODcyfFR5cGU9MQ==&t=1 |
| 18-Sep-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 11-Sep-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk5NjIyfENoaWxkSUQ9NDExMTMwfFR5cGU9MQ==&t=1 |
| 07-Sep-2018 | Enrollment | Number of Subjects Planned Changed from "85" to "100" | 85 | 100 | | | http://wsw.com/webcast/rrshq28/iova/?lobby=true&day=2 |
| 07-Sep-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | http://wsw.com/webcast/rrshq28/iova/?lobby=true&day=2 |
| 07-Sep-2018 | Trial Result | Trial Results Updated | | | | | http://wsw.com/webcast/rrshq28/iova/?lobby=true&day=2 |
| 03-Sep-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 23-Aug-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk4OTQyfENoaWxkSUQ9NDEwMzk2fFR5cGU9MQ==&t=1 |
| 10-Aug-2018 | Study Design/ | Trial Notes | | | | | services.corporate-ir.net/SEC/Docum |

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|---|---|---|---|---|---|---|---|
| | Trial Description | Updated | | | | | ent.Service?id=P3VybD1hSFIwY0RvdkwyRndhUzUwWlc1cmQybDZZWEprTG1OdmJTOWtiM2R1Ykc5aFpDNXdhSEEvWVdOMGFXOXVQVkJFUmlacGNHRm5aVDB4TWpNNU16QTJNQ1p6ZFdKemFXUTlOVGM9JnR5cGU9MiZmbj1Jb3ZhbmNlQmlvdGhlcmFwZXV0aWNzSW5jLnBkZg== |
| 08-Aug-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=RssLanding&cat=news&id=2362261 |
| 03-Aug-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 01-Aug-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 23-Jul-2018 | Acronym/Secondary ID | Trial Secondary ID Updated | | | | | https://www.ukctg.nihr.ac.uk/trials/trial-details/trial-details?trialId=39529&query=%257B%2522query%2522%253A%2522NCT02360579%2522%252C%2522facetDef%2522%253A%257B%2522Trial%2520Status%2522%253A%255B%2522Recruiting%2522%255D%257D%252C%2522rows%2522%253A%252225%2522%252C%2522offset%2522%253A25%252C%2522openurl%2522%253A%2522yes%2522%257D |
| 23-Jul-2018 | Study Design/ Trial | Trial Notes Updated | | | | | |

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|---|---|---|---|---|---|---|---|
| | Description | | | | | | |
| 23-Jul-2018 | Subjects | Trial Subjects Updated | | | | | |
| 12-Jul-2018 | Subjects | Trial Subjects Updated | | | | | |
| 10-Jul-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 06-Jul-2018 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | |
| 06-Jul-2018 | Primary/ Secondary outcomes | Secondary Outcome Measure Updated | | | | | |
| 06-Jul-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 06-Jul-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 22-Jun-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 22-Jun-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 22-Jun-2018 | Study Design/ | Study Design | | | | | |

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|---|---|---|---|---|---|---|---|
| | Trial Description | Updated | | | | | |
| 19-Jun-2018 | Primary/ Secondary outcomes | Secondary Outcome Measure Updated | | | | | http://abstracts.asco.org/214/AbstView_214_229249.html |
| 18-Jun-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 18-Jun-2018 | Acronym/Secondary ID | Trial Secondary ID Updated | | | | | |
| 18-Jun-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 18-Jun-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 14-Jun-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njk1NTA2fENoaWxkSUQ9NDA2NzgxfFR5cGU9MQ==&t=1 |
| 08-Jun-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2353696 |
| 08-Jun-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2353696 |
| 06-Jun-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 30-May- | Study | Trial | | | | | http://ir.iovance.com/phoenix.zhtml |

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|---|---|---|---|---|---|---|---|
| 2018 | Design/ Trial Description | Notes Updated | | | | | ?c=254507&p=irol-newsArticle&ID=2348539 |
| 28-May-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkzNDU3fENoaWxkSUQ9NDA1NjIzfFR5cGU9MQ==&t=1 |
| 21-May-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 14-May-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjkzNDU3fENoaWxkSUQ9NDA0Njc2fFR5cGU9MQ==&t=1 |
| 09-May-2018 | Subjects | Inclusion Criteria Updated | | | | | |
| 07-May-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 07-May-2018 | Trial Date | Trial Estimated End Date Changed from **"01 Jun 2018"** to **"01 Mar 2019"** | 01 Jun 2018 | 01 Mar 2019 | | | |
| 01-May-2018 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | |
| 01-May-2018 | Primary/ Secondary outcomes | Secondary Outcome Measure Updated | | | | | |

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| 01-May-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 01-May-2018 | Subjects | Exclusion Criteria Updated | | | | | |
| 01-May-2018 | Subjects | Inclusion Criteria Updated | | | | | |
| 01-May-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 30-Apr-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 24-Apr-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 19-Apr-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 19-Apr-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 19-Apr-2018 | Subjects | Inclusion Criteria Updated | | | | | |
| 19-Apr-2018 | Trial Result | Trial Results Updated | | | | | |
| 17-Apr- | Study | Trial | | | | | |

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|---|---|---|---|---|---|---|---|
| 2018 | Design/ Trial Description | Description Updated | | | | | |
| 17-Apr-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 17-Apr-2018 | Enrollment | Number of Subjects Planned Changed from "60" to "85" | 60 | 85 | | | |
| 17-Apr-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 17-Apr-2018 | Subjects | Inclusion Criteria Updated | | | | | |
| 17-Apr-2018 | Subjects | Trial Subjects Updated | | | | | |
| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |

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| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 12-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 11-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 11-Apr-2018 | Trial Contacts | Trial Contacts Updated | | | | | |
| 06-Apr-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 03-Apr-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 29-Mar-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 26-Mar-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 20-Mar-2018 | Indications | Trial Indications Updated | | | | | |
| 20-Mar-2018 | Study Design/ Trial Description | Study Design Updated | | | | | |
| 15-Mar-2018 | Study Design/ Trial | Trial Description Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol- |

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|---|---|---|---|---|---|---|---|
| | Description | | | | | | newsArticle&ID=2337617 |
| 15-Mar-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2337617 |
| 14-Mar-2018 | Acronym/Secondary ID | Trial Secondary ID Updated | | | | | |
| 14-Mar-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 14-Mar-2018 | Study Design/ Trial Description | Study Design Updated | | | | | |
| 14-Mar-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 14-Mar-2018 | Subjects | Trial Subjects Updated | | | | | |
| 13-Mar-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 12-Mar-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 12-Mar-2018 | Subjects | Trial Subjects Updated | | | | | |
| 12-Mar-2018 | Study Design/ Trial | Study Design Updated | | | | | |

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| | Description | | | | | | |
| 09-Mar-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 23-Feb-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 22-Feb-2018 | Study Design/ Trial Description | Trial Description Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg4Njk4fENoaWxkSUQ9Mzk5MDIxfFR5cGU9MQ==&t=1 |
| 22-Feb-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg4Njk4fENoaWxkSUQ9Mzk5MDIxfFR5cGU9MQ==&t=1 |
| 22-Feb-2018 | Subjects | Trial Subjects Updated | | | | | |
| 20-Feb-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 14-Feb-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 09-Feb-2018 | Trial Locations | Trial Locations Updated | | | | | |
| 31-Jan-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg3NDAwfENoaWxkSUQ9Mzk3NTc1fFR5cGU9MQ==&t=1 |
| 24-Jan-2018 | Trial Result | Trial Results Updated | | | | | https://jitc.biomedcentral.com/track/pdf/10.1186/s40425-017-0297-3?site=jitc.biomedcentral.com |
| 24-Jan- | Study | Trial | | | | | |

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| 2018 | Design/ Trial Description | Description Updated | | | | | |
| 24-Jan-2018 | Subjects | Inclusion Criteria Updated | | | | | |
| 09-Jan-2018 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njg2Mzg0fENoaWxkSUQ9Mzk2NjEyfFR5cGU9MQ==&t=1 |
| 09-Jan-2018 | Study Design/ Trial Description | Study Design Updated | | | | | |
| 15-Dec-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://globenewswire.com/news-release/2017/12/13/1261171/0/en/Iovance-Biotherapeutics-Announces-Manufacturing-Decision-Provides-Clinical-Updates-and-Highlights-Pipeline-Expansion-at-Analyst-Day-2017.html |
| 15-Dec-2017 | Trial Result | Trial Results Updated | | | | | |
| 15-Dec-2017 | Trial Result | Trial Results Updated | | | | | |
| 15-Dec-2017 | Trial Result | Trial Results Updated | | | | | |
| 14-Dec-2017 | Study Design/ Trial Descripti | Trial Notes Updated | | | | | https://edge.media-server.com/m6/p/fhqnhyoj |

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| | on | | | | | | |
| 14-Dec-2017 | Trial Result | Trial Results Updated | | | | | https://edge.media-server.com/m6/p/fhqnhyoj |
| 06-Dec-2017 | Trial Locations | Trial Locations Updated | | | | | |
| 21-Nov-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://wsw.com/webcast/jeff108/iova/ |
| 14-Nov-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 10-Nov-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 03-Nov-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2312953 |
| 03-Nov-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 03-Nov-2017 | Trial Locations | Trial Locations Updated | | | | | |
| 03-Nov-2017 | Acronym/Secondary ID | Trial Secondary ID Updated | | | | | |
| 02-Nov-2017 | Study Design/ | Trial Notes | | | | | phx.corporate-ir.net/External.Fil |

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|---|---|---|---|---|---|---|---|
| | Trial Description | Updated | | | | | e?item=UGFyZW50SUQ9NjgzMjA1fENoaWxkSUQ9MzkyODA2fFR5cGU9MQ==&t=1 |
| 02-Nov-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 20-Oct-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NjgwMTkxfENoaWxkSUQ9Mzg5NTIxfFR5cGU9MQ==&t=1 |
| 20-Oct-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 10-Oct-2017 | Acronym/Secondary ID | Trial Secondary ID Updated | | | | | |
| 10-Oct-2017 | Drug/Intervention | Secondary Intervention Updated | | | | | |
| 10-Oct-2017 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | |
| 10-Oct-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 10-Oct-2017 | Study Design/ Trial Description | Study Design Updated | | | | | |

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|---|---|---|---|---|---|---|---|
| 10-Oct-2017 | Trial Contacts | Trial Contacts Updated | | | | | |
| 26-Sep-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njc5NjY0fENoaWxkSUQ9Mzg4ODc4fFR5cGU9MQ==&t=1 |
| 21-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 21-Jul-2017 | Trial Result | Trial Results Updated | | | | | |
| 20-Jul-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 14-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 13-Jul-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 13-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 13-Jul-2017 | Study Design/ Trial Description | Study Design Updated | | | | | |

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|---|---|---|---|---|---|---|---|
| 13-Jul-2017 | Sponsor/ Collaborator/CRO | Trial CRO Updated | | | | | |
| 13-Jul-2017 | Enrollment | Number of Subjects Enrolled Changed from "16" to "18" | 16 | 18 | | | |
| 12-Jul-2017 | Trial Result | Trial Results Updated | | | | | http://wsw.com/webcast/jeff105/lbio/?lobby=true&day=1 |
| 04-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 04-Jul-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 04-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 04-Jul-2017 | Subjects | Trial Subjects Updated | | | | | |
| 04-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 03-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9Njc0NjA3fENoaWxkSUQ9MzgyNzk0fFR5cGU9MQ==&t=1 |

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|---|---|---|---|---|---|---|---|
| 03-Jul-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 03-Jul-2017 | Trial Result | Trial Results Updated | | | | | |
| 03-Jul-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 03-Jul-2017 | Study Design/ Trial Description | Study Design Updated | | | | | |
| 22-Jun-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | http://www.marketwired.com/press-release/lion-biotechnologies-announces-updated-data-2017-american-society-clinical-oncology-nasdaq-lbio-2220056.htm |
| 22-Jun-2017 | Subjects | Trial Subjects Updated | | | | | |
| 22-Jun-2017 | Subjects | Trial Subjects Updated | | | | | |
| 09-Jun-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://abstracts.asco.org/199/AbstView_199_185466.html |
| 09-Jun-2017 | Subjects | Trial Subjects Updated | | | | | http://abstracts.asco.org/199/AbstView_199_185466.html |
| 09-Jun-2017 | Trial Result | Trial Results | | | | | http://abstracts.asco.org/199/AbstView_199_18546 |

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|---|---|---|---|---|---|---|---|
| | | Updated | | | | | 6.html, http://www.marketwired.com/press-release/lion-biotechnologies-announces-updated-data-2017-american-society-clinical-oncology-nasdaq-lbio-2220056.htm |
| 09-Jun-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 09-Jun-2017 | Enrollment | Number of Subjects Analyzed Changed from "16" to "9" | 16 | 9 | | | |
| 09-Jun-2017 | Enrollment | Number of Subjects Enrolled Changed from "16" to "9" | 16 | 9 | | | |
| 09-Jun-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 05-Jun-2017 | Trial Date | Trial Estimated End Date Changed from **"01 Jan 2018"** to **"01 Jun 2018"** | 01 Jan 2018 | 01 Jun 2018 | | | |
| 05-Jun-2017 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | |

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|---|---|---|---|---|---|---|---|
| 05-Jun-2017 | Primary/ Secondary outcomes | Secondary Outcome Measure Updated | | | | | |
| 05-Jun-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 05-Jun-2017 | Subjects | Exclusion Criteria Updated | | | | | |
| 05-Jun-2017 | Subjects | Inclusion Criteria Updated | | | | | |
| 05-Jun-2017 | Enrollment | Number of Subjects Planned Changed from "40" to "60" | 40 | 60 | | | |
| 05-Jun-2017 | Trial Contacts | Trial Contacts Updated | | | | | |
| 23-May-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://content.equisolve.net/lbio/news/2017-05-19_Lion_Biotechnologies_Announces_First_Patient_97.pdf |
| 23-May-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 18-May-2017 | Subjects | Trial Subjects Updated | | | | | https://clinicaltrials.gov/ct2/show/NCT02360579?term=NCT02360579&rank=1 |
| 17-May-2017 | Study Design/ Trial | Trial Notes Updated | | | | | http://ir.lbio.com/all-sec-filings/content/0001144204-17- |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | Description | | | | | | 024234/0001144204-17-024234.pdf |
| 25-Apr-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 25-Apr-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 24-Apr-2017 | Trial Locations | Trial Locations Updated | | | | | |
| 24-Apr-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | |
| 24-Apr-2017 | Trial Contacts | Trial Contacts Updated | | | | | |
| 27-Mar-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://www.wsw.com/webcast/coweb38/lbio/?lobby=true&day=1 |
| 23-Mar-2017 | Enrollment | Number of Subjects Planned Changed from "20" to "40" | 20 | 40 | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Primary/ Secondary outcomes | Primary Outcome Measure Updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Primary/ Seconda | Secondary Outcome | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017 |

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|---|---|---|---|---|---|---|---|
| | ry outcomes | Measure Updated | | | | | _02_28/changes |
| 23-Mar-2017 | Study Design/ Trial Description | Study Design Updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Study Design/ Trial Description | Trial Description Updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://investor.anthera.com/secfiling.cfm?filingID=1214659-17-2018&CIK=1316175 |
| 23-Mar-2017 | Subjects | Exclusion Criteria Updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Subjects | Inclusion Criteria Updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Trial Contacts | Trial Contacts Updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 23-Mar-2017 | Trial Date | Trial Estimated End Date Changed from **"01 Sep 2018"** to **"01 Jan 2018"** | 01 Sep 2018 | 01 Jan 2018 | | | https://clinicaltrials.gov/archive/NCT02360579/2017_02_28/changes |
| 09-Mar-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | http://www.lbio.com/news-media/press-releases/detail/90/lion-biotechnologies-reports-fourth-quarter-and-full-year |

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|---|---|---|---|---|---|---|---|
| 20-Feb-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 20-Feb-2017 | Study Design/ Trial Description | Trial Notes Updated | | | | | |
| 18-Jan-2017 | Miscellaneous | Trial notes updated; | | | | | http://c.eqcdn.com/_e05c3f35ad3f18a8dfe6b487716f1d1d/lbio/db/230/543/pdf/Lion+Investor+Pres-+Jan+2017-+FINAL+1.7+9am.pdf |
| 05-Dec-2016 | Miscellaneous,Trial Locations | Study period updated; Location and contact details updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2016_11_28/changes |
| 02-Nov-2016 | Miscellaneous,Trial Locations | Locations details updated; Contact and investigator details updated | | | | | |
| 24-Oct-2016 | Miscellaneous,Trial Locations | Trial location details updated; Trial contact details updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2016_10_10/changes |
| 09-Aug-2016 | Miscellaneous,Su | Official Title | | | | | https://clinicaltrials.gov/archive/NCT02360579/2016_08_07/changes |

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|---|---|---|---|---|---|---|---|
| | bjects | updated; Subjects type updated; Trial secondary outcomes updated;Subjects age criteria updated; Trial inclusion criteria updated; Trial exclusion criteria updated; Contact details updated | | | | | |
| 08-Jul-2016 | Enrollment,Miscellaneous | Study enrollment , description and study design updated | | | | | http://wsw.com/webcast/jeff97/lbio/?lobby=true |
| 05-Jul-2016 | Miscellaneous,Trial Locations | Trial location details Updated ; Trial contact details Updated ; Trial P.I details Updated ; | | | | | https://clinicaltrials.gov/archive/NCT02360579/2016_06_30/changes |
| 15-Jun-2016 | Miscellaneous,Subjects | Contact details updated; Subject | | | | | https://clinicaltrials.gov/archive/NCT02360579/2016_06_13/changes |

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|---|---|---|---|---|---|---|---|
| | | type updated | | | | | |
| 18-Mar-2016 | Subjects | Subject type updated | | | | | https://clinicaltrials.gov/ct2/show/NCT02360579?term=NCT02360579&rank=1 |
| 15-Feb-2016 | Trial Locations | Subject Types updated | | | | | |
| 25-Nov-2015 | Trial Locations | Location details updated | | | | | |
| 18-Nov-2015 | Trial Locations | Location details updated | | | | | https://clinicaltrials.gov/archive/NCT02360579/2015_11_12/changes |
| 21-Sep-2015 | Trial Locations | Locations added | | | | | https://clinicaltrials.gov/archive/NCT02360579/2015_09_14/changes |
| 16-Sep-2015 | Trial Date,Trial Status | Trial status changed to "Ongoing, recruiting"; Actual start date added | | | | | http://lbio.com/press_releases/lion-biotechnologies-opens-enrollment-in-phase-2-study-of-ln-144-for-the-treatment-of-refractory-metastatic-melanoma/ |
| 03-Sep-2015 | Trial Date | Trial End date changed to "2015-10" | | | | | https://clinicaltrials.gov/archive/NCT02360579/2015_08_31/changes |

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