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Clinical Trial Information			
Trial Title	Study of Effectiveness of Axicabtagene Ciloleucel Compared to Standard of Care Therapy in Patients with Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)		
Drug(s)/Molecule(s)	axicabtagene ciloleucel;	**Trial Identifier**	GDCT0222288
Secondary ID(s)	GDC40002568; NCT03391466;KTE-C19-107;2017-002261-22;EudraCT-2017-002261-22;016278;NCI-2018-00042;UMGCC1818GCCC;1818GCCC;TEC-C19-107;OSU-17326;20729;2018-008;19341;SNCTP000003107;KTE-C19-107 (ZUMA-7);2018-01359;MOH_2018-08-07_002200;17-541;2017-0699;113165;XX-0051;IND-016278;BASEC2018-01359		
Sponsor (s)	Kite Pharma Inc	**Indication**	B-Cell Non-Hodgkin Lymphoma, Diffuse Large B-Cell Lymphoma, Non-Hodgkin Lymphoma
Trial Status	Completed	**Trial Phase**	Phase III
Data Monitoring Committee	YES		
Approved Health Authority	Austria: Austrian Federal Office for Safety in Health Care (BASG); Belgium: Federal Public Service (FPS) Health - Directorate-General Medicines (DGM); France: National Agency of Medicine and Health Product Safety (ANSM); Spain: Spanish Agency of Medicines and Medical Devices (AEMPS); Sweden: Medical Products Agency (MPA); United Kingdom: Medicines and Healthcare products Regulatory Agency (MHRA); Germany: Paul-Ehrlich-Institut (PEI); The Netherlands: Netherlands Competent Authority		
Secondary Intervention	autologous stem cells, BEAM [carmustine + cytarabine hydrochloride + etoposide + melphalan], cyclophosphamide, fludarabine, gemcitabine hydrochloride, R-DHAP [rituximab + dexamethasone + cytarabine + cisplatin], R-ESHAP [cisplatin + cytarabine + etoposide + methylprednisolone + rituximab], R-ICE [etoposide + ifosfamide + carboplatin + rituximab]		

Clinical Trial Details	
Trial Title	Study of Effectiveness of Axicabtagene Ciloleucel Compared to Standard of Care Therapy in Patients with Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)
Official Title	A Phase 3, Randomized, Open-Label Study Evaluating the Efficacy of Axicabtagene Ciloleucel Versus Standard of Care Therapy in Subjects With Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)

Acronym	ZUMA-7, ZUMA 7
Study Type	Interventional
Therapy Type	Combination Therapy
Actual Start Date	25 Jan 2018
Actual End Date	18 Mar 2021
Trial Duration (in Months)	38.27
Study Designs	
Purpose	The purpose of the study was to assess whether axicabtagene ciloleucel therapy improved the clinical outcome compared with standard of care second-line therapy in subjects with relapsed/refractory diffuse large B-cell lymphoma.
Primary Outcome Measure(s)/Objective(s)	• To assess the clinical survival benefits and additional safety of KTE-C19 • Event Free Survival (EFS) Per Blinded Central Assessment - From randomization date up to a median follow-up: 24.9 months o EFS: Time from randomization to disease progression (PD), best response of SD up to and including Day 150, commencement of subsequent new anti-lymphoma therapy including stem cell transplant, or death from any cause. PD=score 4 (uptake moderately>liver)/5 (uptake markedly >liver and/or new lesions) with an increase in intensity of uptake from baseline; new fluorodeoxyglucose (FDG)-avid foci consistent with lymphoma at interim/EOT assessment, rather than another etiology or in bone marrow; an individual node/lesion must be abnormal with LDi >1.5 cm, increase by ≥50% from cross-product of LDi and perpendicular diameter nadir, increase in LDi or shortest axis perpendicular to LDi from nadir, splenic length must increase by >50% of extent of its prior increase beyond Baseline. If no prior splenomegaly, increase must be ≥2 cm from baseline; new/recurrent splenomegaly; new/clear progression of pre-existing NMLs; new lesion; new/recurrent bone marrow involvement. KM estimates was used for analysis
Secondary Outcome Measure(s)/Objective(s)	• EFS based on investigator disease assessments • Progression-free survival • Duration of response (DOR) and complete response • Incidence of adverse events and clinically significant changes in safety lab values including antibodies to axicabtagene ciloleucel • Changes from screening to post baseline in the global health status QoL scale and the physical functioning domain of the EORTC QLQ-C30 • Changes from screening to post baseline in the EQ-5D-5L index and VAS

	scores • PFS, duration of response, safety, and pt-reported outcomes • PROs (HRQoL, EQ5D - 5L, QLQ - C30) • Objective Response Rate (ORR) Per Blinded Central Assessment - From randomization date up to a median follow-up: 24.9 months o ORR: Percentage of participants with CR [CMR;CRR] or PR [partial metabolic response (PMR); partial radiologic response (PRR)].CMR: PET 5PS scores of 1 (no uptake above background, 2(uptake≤mediastinum), 3(uptake>mediastinum but≤liver) with/without a residual mass; no new lesions; no evidence of FDG-avid disease in BM. CRR: target nodes/nodal masses regressed to ≤ 1.5 cm in LDi; no extralymphatic sites of disease; absent non-measured lesions (NMLs);organ enlargement regress to normal; no new sites;bone marrow morphology normal. PMR: scores 4 (uptake moderately>liver),5(uptake markedly > liver, new lesions) with reduced uptake compared with baseline and residual mass; no new lesions; responding disease at interim/residual disease at end of treatment (EOT).PRR: ≥50% decrease in sum of the product of perpendicular diameters (SPD) of up to 6 target measurable nodes and extra-nodal sites; absent/normal, regressed, but no increase of NMLs;spleen regressed by >50% in length beyond normal; no new sites • Overall Survival (OS) - From randomization date up to a median follow-up: 47.2 months o Overall survival is defined as the time from randomization to death from any cause. Kaplan-Meier (KM) estimates was used for analysis • Duration of Response (DOR) Per Blinded Central Assessments - From the date of first confirmed objective response (CR or PR) to disease progression or death regardless of cause (Up to 37.8 months) o DOR is defined only for participants who experience an objective response after axicabtagene ciloleucel infusion and is the time from the first objective response per Lugano classification to disease progression or death from any cause. Objective response is defined in outcome measure 2 and disease progression is defined in outcome measure 1. KM estimates were used for analysis • Modified Event Free Survival (mEFS) Per Blinded Central Assessment - From randomization date up to a median follow-up: 24.9 months o Modified event free survival is defined the same way as EFS, except that a best response of SD up to and including Day 150 assessment post randomization was not considered an event. KM estimates were used for analysis

	• Event Free Survival Per Investigator Disease Assessments - From randomization date up to a median follow-up: 47.2 months o EFS was defined as the time from randomization to the earliest date of disease progression per the IWG Lugano Classification, best response of stable disease (SD) up to and including Day 150, commencement of new lymphoma therapy, or death from any cause. Disease progression is defined in outcome measure 1 • Progression-Free Survival (PFS) Per Investigator Disease Assessments - From randomization date up to a median follow-up: 47.2 months o PFS is defined as the time from the randomization date to the date of disease progression per Lugano classification or death from any cause. Disease progression is defined in outcome measure 1. KM estimates was used for analysis • Modified Event Free Survival (mEFS) Per Investigator Assessment - From randomization date up to a median follow-up: 47.2 months o Modified event free survival is defined the same way as EFS, except that a best response of SD up to and including Day 150 assessment post randomization was not considered an event. KM estimates were used for analysis • Change From Baseline in Global Health Status Scores - Baseline, Days 50, 100, and 150; Months 9, 12, 15, 18, 21 and 24 o Global health status was measured using European Organization for Research and Treatment of Cancer (EORTC) Quality Life Questionnaire (QLQ) C-30. This health related quality of life (HRQoL) questionnaire was comprised of 15 questions on functional scales, 13 questions on symptom scales and 2 on global health status scale. Global Health Status used a 7 point Likert-type scale of 1 (Very poor) to 7 (Excellent). All scores were transformed to 0-100. Higher scores for Global Health Status indicated better HRQoL • Change From Baseline in EORTC QLQ-C30 Physical Functioning Score - Baseline, Days 50, 100, 150, Months 9, 12, 15, 18, 21 and 24 o The EORTC QLQ-C30 is composed of global health status/QoL scale; five functional domains (physical, role, emotional, cognitive, and social); three symptom domains (fatigue, nausea and vomiting, and pain); and six single items (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties) o The Physical Functioning domain includes 5 questions in which participants were asked to rate their overall health and overall quality of life as it relates to physical functioning during the past week on a scale from 1 (very poor) to 7 (excellent). The 5 scores

	were transformed to a scale from 0 to 100, where a high score indicated better QoL. A positive change from baseline indicates better QoL • Changes From Baseline in the European Quality of Life Five Dimensions Five Levels Scale (EQ-5D-5L) Index Score - Baseline, Days 50, 100, 150; Months 9, 12, 15, 18, 21 and 24 o The Euro-QOL, Five Dimensions, Five Levels (EQ-5D-5L) questionnaire is a generic measure of health status that provides a simple descriptive profile and a single index value. The EQ-5D-5L comprises 2 components: a questionnaire covering 5 dimensions and a tariff of values based upon direct valuations of health states using a visual analog scale (VAS). The total score for EQ-5D-5L index- is presented on a range from 0 to 1 where higher scores indicate better outcome. A positive change from Baseline indicates improvement • Change From Baseline in EQ-5D-5L VAS Scale Score - Baseline, Days 50, 100, 150; Months 9, 12, 18, 21 and 24 o The EQ-5D-5L VAS is a 20-cm VAS for recording self-rated current HRQoL state and is used to describe the participants' health status on the day of the assessment. The EQ-5D-5L VAS score is recorded by each participant for his or her current HRQoL state and scored 0 ("the worst health you can imagine") to 100 ("the best health you can imagine"). The value 100 indicates improvement • Number of Participants With Anti-Axicabtagene Ciloleucel Antibodies - From first dose of axicabtagene up to a median follow-up: 24 months • Percentage of Participants Experiencing Treatment-emergent Adverse Events - Up to 5 years o A TEAE is defined as any AE that begins on or after the first dose of study treatment (axicabtagene ciloleucel infusion or SOC), excluding bridging therapy. Participant incidence rates of TEAEs, including all, serious, fatal, CTCAE Grade 3 or higher, and treatment related AEs reported will be tabulated by preferred term and system organ class coded with the Medical Dictionary for Regulatory Activities (MedDRA) • Percentage of Participants With Clinically Significant Changes in Laboratory Values Reported as Grade 3 or Higher TEAEs - Up to 5 years o Grading categories were determined by Common Terminology Criteria for Adverse Events (CTCAE) version 4.03. Grade 1: mild, Grade 2: moderate, Grade 3: severe or medically significant, Grade 4: life-threatening

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Changes Over Time in the European Quality of Life Five Dimensions Five Levels Scale (EQ-5D-5L) - Up to 5 years

The Euro-QOL, Five Dimensions, Five Levels (EQ-5D-5L) questionnaire is a generic measure of health status that provides a simple descriptive profile and a single index value. The EQ-5D-5L comprises 2 components: a questionnaire covering 5 dimensions and a tariff of values based upon direct valuations of health states using a visual analog scale (VAS)

Changes Over Time in the Visual Analog Scale (VAS) Scores - Up to 5 years
The EQ-5D-5L VAS is a 20-cm VAS for recording self-rated current HRQoL state and is used to describe the subjects' health status on the day of the assessment. The EQ-5D-5L VAS score is recorded by each subject for his or her current HRQoL state and scored 0 ("the worst health you can imagine") to 100 ("the best health you can imagine")

Exploratory endpoint:

Level of CAR T cells
Other endpoints included OS in key subgroups and safety
Axi-cel pharmacokinetics and product features
To determine the association between OS and axi-cel product characteristics for pts aged ≥65 y.

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<td>Trial Description</td>
<td>This was an interventional, phase III, global, randomized, active controlled, pivotal/registrational, pharmacoeconomics, two arm, confirmatory, head to head, international, parallel assignment, open-label, treatment, superiority and multi-centered, largest and longest study to assess whether axicabtagene ciloleucel therapy improves the clinical outcome compared with standard of care second-line therapy in subjects with relapsed/refractory diffuse large B-cell lymphoma (DLBCL). Subjects were randomized in a (1:1) ratio into two arms:
<table>
<tr><th>Arm</th><th>Type</th><th>Assigned Intervention</th><th>Description</th></tr>
<tr><td>I (n=180)</td><td>Experimental</td><td>Axicabtagene Ciloleucel</td><td>Subjects received cyclophosphamide at a dose of 500 mg/m^2/day intravenously (IV) and fludarabine 30 mg/m^2/day IV conditioning chemotherapy for 3 days followed by axicabtagene ciloleucel administered as a single IV infusion at a target dose of 2 x 10^6 anti-cluster of differentiation antigen (CD) 19 CAR transduced autologous T cells/kg on Day 0.</td></tr>
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II (n=179)	Active Comparator (standard of care)	Platinum-containing salvage chemotherapy (R-ICE, BEAM), Autologous stem cell	Subjects received 2 or 3 21-day cycles of second-line chemotherapy regimen; R-ICE: rituximab 375 mg/m^2 before chemotherapy, ifosfamide 5 g/m^2 24hour(hr) infusion on Day 2+mesna,carboplatin area under the curve (AUC) 5 on Day 2, maximum dose 800 mg, etoposide 100 mg/ m^2/day on Days 1-3; R-ESHAP: rituximab 375 mg/m^2 Day 1,etoposide 40 mg/m^2/day IV on Days 1-4,methylprednisolone 500 mg/day IV on Days 1-4 or 5,cisplatin at 25 mg/m^2/day Days 1-4,cytarabine 2 g/m^2 on Day 5; R-GDP: rituximab 375 mg/m^2 Day 1(or Day 8),gemcitabine 1g/m^2 on Days 1 and 8,dexamethasone 40 mg on Days 1-4,cisplatin 75mg/m^2 on Day 1 or carboplatin AUC=5; or R-DHAP: Rituximab 375 mg/ m^2 before chemotherapy, dexamethasone 40 mg/day on Days 1-4,highdose cytarabine 2 g/m^2 every 12 hours for 2 doses on Day 2 following/platinum, cisplatin 100 mg/m^2 24hr infusion on Day 1 or oxaliplatin 100 mg/m^2. Participants who will respond will get high dose therapy and autologous stem cell transplant.

Standard of care consisted of a protocol-defined, platinum-based salvage combination chemotherapy regimen followed by high-dose therapy and autologous stem cell transplant in those who respond to salvage chemotherapy. The end of study was defined as when the last subject was assessed or received an intervention for evaluation in the study, including survival assessments. Study evaluates the safety and efficacy of Yescarta versus SOC for initial treatment of adult subjects with R/R LBCL within 12 months of first-line therapy.

Subjects were stratified by 1L Tx response and 2L age-adjusted IPI (sAAIPI). In the axi-cel arm, subjects received a single infusion of 2×106 CAR T cells/kg after conditioning (3 d; cyclophosphamide 500 mg/m2/day and fludarabine 30 mg/m2/day). Optional bridging Tx was limited to corticosteroids (CIT was not allowed).

In the SOC arm, subjects received 2–3 cycles of an investigator-selected, protocol defined, platinum-based CIT regimen; subjects with partial response or complete

	response (CR) proceeded to HDT-ASCT. Disease assessments by PET-CT per Lugano Classification occurred at timepoints specified from randomization. Although there was no planned study crossover between arms, subjects not responding to SOC could received CAR T-cell therapy off protocol. Axi-cel was hypothesized to result in a 50% improvement in event-free survival (EFS: time to earliest date of disease progression, death from any cause, or new lymphoma Tx) vs SOC. Serum samples were collected from peripheral blood at the time of leukapheresis. Subjects were randomized to axi-cel or SOC (2-3 cycles of chemotherapy followed by high-dose therapy with autologous stem cell transplant [ASCT] for those with partial response [PR] or complete response [CR]). The subsequent third-line (3L) therapy was classified as chemotherapy or cellular immunotherapy (axi-cel arm: axi-cel retreatment on protocol for subjects who initially responded to axi-cel) After completing the treatment period, all subjects were followed in the post-treatment follow-up period for up to 5 years. Thereafter, subjects who received at least one dose of axicabtagene ciloleucel as protocol therapy transitioned to a separate long term follow up (LTFU) study and complete the remainder of the 15-year follow-up assessments within KT-US-982-5968 (NCT05041309). A total of 359 subjects were enrolled in the study.
Trial Notes	As of March 2023, findings are expected to be presented in full at an upcoming scientific meeting later this year. https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract As per the first quarter 2021 financial results presentation April 2021, the study phase 3 data readout expected in first half of 2021. http://investors.gilead.com/static-files/9fc6ee8f-b63c-451b-a8a8-9136bdcfc54c (Slide no: 05) As per the first quarter 2021 summary of prepared remarks report April 2021, the study phase 3 data readout expected in first half of 2021. http://investors.gilead.com/static-files/8c2b2e71-5dc3-44cf-92f1-7e3469567a56 (Page no: 03) As per the first quarter 2021 earnings conference call report April 2021, the study topline data expected in later this quarter. http://investors.gilead.com/static-files/0f60561c-9411-4fd7-b555-15e3cbdd293a(Page no: 07) As per the first quarter report (FORM 10-Q) March 2021, the study data readout expected in 2021. http://investors.gilead.com/static-files/8d6790d3-aadf-4109-8ac7-a85c435e8262(Page no: 44) As per the Fourth Quarter and Full Year 2020 Financial Results Presentation February 2021, the study data read-out expected in first half of 2021. http://investors.gilead.com/static-files/079f6f7e-62bb-44c9-88e9-64b48d9be9f5 (Slide no: 42) As per the company presentation at the Virtual 39th Annual JP Morgan Healthcare Conference, study data read-out expected in first half of 2021. http://investors.gilead.com/static-files/da2a6be6-1c7a-4769-aa73-8f00408c91a3(Slide 21) As per the third quarter 2020 results presentation

	October 2020, the study data expected in 2021. http://investors.gilead.com/static-files/7db4987f-930d-4b18-877e-0c75d5e34c0d(Slide no: 22) As per the first half and second quarter 2020 earnings results presentation July 2020, the study data expected in the second half of 2020. http://investors.gilead.com/static-files/cd67608e-573e-4a6a-8131-aee5b9e2453e(Slide no: 26) As per the first quarter 2020 earnings results presentation April 2020, the phase 3 study data expected in second half of 2020. http://investors.gilead.com/static-files/af4599eb-4fb8-4cf7-96a1-38caf477e9b4(Slide no: 57) As per the fourth quarter 2019 earnings results presentation February 2020, the phase 3 study data expected in second half of 2020. http://investors.gilead.com/static-files/36dc002c-bce8-4242-b087-f4e388d6b606 (Slide no: 08) As per the second quarter 2019 earnings results presentation July 2019, study enrollment completion expected in fourth quarter of 2019. http://investors.gilead.com/static-files/575b248b-e0bc-4220-9386-e3f555cacc79 (Slide No: 41) As per the First Quarter 2019 Earnings Results Presentation May 2019, the study enrollment completion expected in fourth quarter of 2019. http://investors.gilead.com/static-files/ead8235f-ab4e-4d0e-b354-453b3d6820a2 (Slide No: 53) As per the fourth quarter 2018 earnings results presentation January 2018, the study enrollment completion expected in second half of 2019. http://investors.gilead.com/static-files/d37c8017-5ae2-40d1-b8e3-371604c33341 (Slide No. 64) As per the second quarter 2018 earnings results presentation July 2018, enrollment completion expected in second half of 2019. phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NDA4OTU1fENoaWxkSUQ9LTF8VHlwZT0z&t=1&cb=636680582523475446 (Slide No: 43) As per the company presentation at the Jefferies 2017 Global Healthcare Conference, first subject enrollment expected in 2017. http://wsw.com/webcast/jeff105/kite/?lobby=true&day=2 (Slides 22,24) As per company corporate presentation June 2017, first subject enrollment expected in 2017. http://files.shareholder.com/downloads/AMDA-2V2XOY/3931323970x0x945757/29F0F521-5728-4871-AB18-3F8519098BB7/Kite_Corporate_Presentation_-_June_2017.pdf (Slides 22,24,27) As per the company corporate presentation April 2017, first subject enrollment expected in 2017. http://files.shareholder.com/downloads/AMDA-2V2XOY/4314053637x0x931905/DFBB279C-1240-420C-B5B6-FC7A5B4EFC01/KITE_Corporate_Presentation_-_April_2017.pdf(Slide No. 12) As per the company presentation at the 37th Cowen and Company Annual Health Care Conference, first subject enrollment expected in 2017. http://wsw.com/webcast/cowen38/kite/ (Slides 08,09,25) As per the corporate presentation, March 2017, first subject enrollment expected in 2017. http://files.shareholder.com/downloads/AMDA-2V2XOY/3905183343x0x931905/DFBB279C-1240-420C-B5B6-

	FC7A5B4EFC01/KITE_Corporate_Presentation_-_March_2017.pdf (Slide 8) As per annual report (FORM 10-K) 2016, study initiation expected in 2017. http://files.shareholder.com/downloads/AMDA-2V2XOY/3931323970x0xS1510580%2D17%2D3/1510580/filing.pdf (pages 9) As per the company presentation at the 35th Annual J.P. Morgan Healthcare Conference, the first subject enrollment expected in 2017. http://files.shareholder.com/downloads/AMDA-2V2XOY/3690731638x0x923850/0DDC9807-9379-4C1F-9FBB-C0293699C109/Kite_Pharma_-_JP_Morgan_Presentation_.pdf (Pages 12,29) As per the Investor Day presentation 2016, the first subject was planned to be enrolled in 2017. files.shareholder.com/downloads/AMDA-2V2XOY/3473479470x0x915808/BBCD802C-ECE9-4848-B1B6-8D34D532E12C/KitePharma_Investor_Day_Presentation_-_10.18.16.pdf (Slide No: 75) As per the Stifel Healthcare Conference 2016, the first subject was planned to be enrolled in 2017. http://wsw.com/webcast/stifel5/kite/ (Slide No: 15) As per third quarter report (FORM 10-Q) 2016, the study was expected to be initiated in 2017. http://files.shareholder.com/downloads/AMDA-2V2XOY/3240970821x0xS1510580%2D16%2D4/1510580/filing.pdf (Page 27) As of October 2016, first subject was expected to be enrolled in 2017. http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338 As per the company presentation at the 36th Canaccord Genuity Annual Growth Conference, the study was expected to be initiated in 2016. http://wsw.com/webcast/canaccord23/kite/?lobby=true&day=1 As per the S-1 registration statement (filed on May 19th, 2014), trial was expected to be initiated in 2016. As per the second quarter report (FORM 10-Q) 2014, trial was expected to be initiated in 2015. As per the Full-Year and Fourth Quarter 2014 Financial Results, trial was expected to be initiated in 2015. As per the company presentation at the 2015 Jefferies Immuno-Oncology Summit, trial was expected to be initiated in 2015. As per the company presentation at the Cowen and Company 35th Annual Healthcare Conference, planned to initiate the study in first half of 2015. As per the company presentation August 2015, trial was expected to be initiated in 2015. As per the company presentation September 2015, trial was expected to be initiated in the second half of 2015.

Sponsor(s)/Collaborator(s)	
Sponsor(s) - Type & Details	
Sponsor	Kite Pharma Inc (Subsidiary of Gilead Sciences Inc)

Drug Details

Primary Interventions(s)

Generic Name	Route of Administration
axicabtagene ciloleucel	Intravenous

Secondary Interventions(s)

Generic Name	Route of Administration
gemcitabine hydrochloride	Intravenous
autologous stem cells	
cyclophosphamide	
fludarabine	
BEAM [carmustine + cytarabine hydrochloride + etoposide + melphalan]	
R-ICE [etoposide + ifosfamide + carboplatin + rituximab]	
R-DHAP [rituximab + dexamethasone + cytarabine + cisplatin]	
R-ESHAP [cisplatin + cytarabine + etoposide + methylprednisolone + rituximab]	

Drug Name

axicabtagene ciloleucel (Pipeline Drug)

Drug Description

Axicabtagene ciloleucel (KTE-C19 / Yescarta / Yikaida) is human culture expanded genetically modified autologous T cells for cell-based gene therapy. Cells are derived from isolated blood of the patient and are transduced with non-replicative retroviral vector encoding the FMC63 anti-CD19 single chain variable fragment (scFv) CD28/CD3zeta chimeric antigen receptor (FMC63-28Z CAR). It is formulated as suspension for intravenous route of administration. It is indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. It is also indicated for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. Yescarta is indicated for adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. It is under development for the treatment of solid tumors, indolent non-Hodgkin lymphoma, diffuse large B cell lymphoma (DLBCL), lymph node and extranodal marginal zone B-cell lymphoma, primary mediastinal B-cell lymphoma(PMBCL), mantle cell lymphoma, recurrent chronic

	lymphocytic leukemia, refractory chronic lymphocytic leukemia, acute lymphocytic leukemia, burkitt lymphoma, refractory acute myeloid leukemia, follicular lymphoma, high grade B-cell lymphoma and large cell lymphoma. It was also under development for the treatment acute lymphoblastic leukemia and mantle cell lymphoma.
Mechanism of Action	Yescarta, a CD19-directed genetically modified autologous T cell immunotherapy, binds to CD19-expressing cancer cells and normal B cells. Anti-CD19 CAR T cell engagement with CD19-expressing target cells, causes the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.
ATC Classification	L01XL Antineoplastic cell and gene therapy
Target	B Lymphocyte Antigen CD19 (B Lymphocyte Surface Antigen B4 or Differentiation Antigen CD19 or T Cell Surface Antigen Leu 12 or CD19)
Drug Name	axicabtagene ciloleucel (Marketed Drug)
Mechanism of Action	Yescarta, a CD19-directed genetically modified autologous T cell immunotherapy, binds to CD19-expressing cancer cells and normal B cells. Anti-CD19 CAR T cell engagement with CD19-expressing target cells, causes the CD28 and CD3-zeta co-stimulatory domains activate downstream signaling cascades that lead to T-cell activation, proliferation, acquisition of effector functions and secretion of inflammatory cytokines and chemokines. This sequence of events leads to killing of CD19-expressing cells.
ATC Classification	L03AX Other immunostimulants
Target	B Lymphocyte Antigen CD19 (B Lymphocyte Surface Antigen B4 or Differentiation Antigen CD19 or T Cell Surface Antigen Leu 12 or CD19)

Patient Details

Age	**Minimum Age Eligibility**: 18 Years **Maximum Age Eligibility**:
Gender	Both
Healthy Subject(s)	No
Subject(s) Type	Adults, Aggressive Disease, Anthracycline Treated, Biopsy Proven Disease, Chronic Disease, Complete Remission, Cutaneous Disease, Diffuse Disease, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status
Participant Criteria	• Histologically proven large B-cell lymphoma including the following

(Inclusion)	types defined by World Health Organization (WHO) 2016. o Diffuse large B-cell lymphoma (DLBCL) not otherwise specified activated B-cell/ germinal center B-cell (ABC/GCB) o High-grade B-cell lymphoma (HGBL) with or without myelocytomatosis oncogene (MYC) and B-cell lymphoma (BCL) 2 and/or BCL6 rearrangement o DLBCL arising from follicular lymphoma (FL) o T-cell/histiocyte rich large B-cell lymphoma o DLBCL associated with chronic inflammation o Primary cutaneous DLBCL, leg type o Epstein-Barr virus (EBV) + DLBCL • Relapsed or refractory disease after first-line chemoimmunotherapy o Refractory disease defined as no complete remission to first-line therapy; individuals who are intolerant to first-line therapy are excluded. ▪ Progressive disease (PD) as best response to first-line therapy ▪ Stable disease (SD) as best response after at least 4 cycles of first-line therapy (eg, 4 cycles of R-CHOP or R-EPOCH) ▪ Partial response (PR) as best response after at least 6 cycles and biopsy-proven residual disease or disease progression ≤ 12 months of therapy o Relapsed disease defined as complete remission to first-line therapy followed by biopsy-proven relapse ≤ 12 months of first-line therapy • Individuals must have received adequate first-line therapy including at a minimum: o Anti-Cluster of Differentiation antigen (CD) 20 monoclonal antibody unless investigator determines that tumor is CD20 negative, and o An anthracycline containing chemotherapy regimen • No known history or suspicion of central nervous system involvement by lymphoma • Eastern cooperative oncology group (ECOG) performance status of 0 or 1 o Adequate bone marrow function as evidenced by: o Absolute neutrophil count (ANC) ≥ 1000/ul o Platelet ≥ 75,000/ul • Absolute lymphocyte count ≥ 100/ul • Adequate renal, hepatic, cardiac, and pulmonary function as evidenced by:

	○ Creatinine clearance (Cockcroft Gault) ≥ 60 mL/min ○ Serum Alanine aminotransferase/Aspartate aminotransferase (ALT/AST) ≤ 2.5 Upper limit of normal (ULN) ○ Total bilirubin ≤ 1.5 mg/dl ○ Cardiac ejection fraction ≥ 50%, no evidence of pericardial effusion as determined by an Echocardiogram (ECHO), and no clinically significant Electrocardiogram (ECG) findings ○ No clinically significant pleural effusion • Baseline oxygen saturation > 92% on room air • Intended to proceed to HDT-ASCT • Median 3 prior lines of therapy • Females of childbearing potential must have a negative serum or urine pregnancy test (females who have undergone surgical sterilization or who have been postmenopausal for at least 2 years are not considered to be of childbearing potential)
Participant Criteria (Exclusion)	• History of malignancy other than nonmelanoma skin cancer or carcinoma in situ (eg cervix, bladder, breast) unless disease free for at least 3 years • Received more than one line of therapy for DLBCL • History of autologous or allogeneic stem cell transplant • Presence of fungal, bacterial, viral, or other infection that is uncontrolled or requiring intravenous antimicrobials for management. • Known history of infection with human immunodeficiency virus (HIV) or hepatitis B (HBsAg positive) or hepatitis C virus (anti-HCV positive). If there is a positive history of treated hepatitis B or hepatitis C, the viral load must be undetectable per quantitative polymerase chain reaction (PCR) and/or nucleic acid testing. • Individuals with detectable cerebrospinal fluid malignant cells or known brain metastases, or with a history of cerebrospinal fluid malignant cells or brain metastases. • History or presence of non-malignant central nervous system (CNS) disorder such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or any autoimmune disease with CNS involvement • Presence of any indwelling line or drain. Dedicated central venous access catheter such as a Port-a-Cath or Hickman catheter are permitted. • History of myocardial infarction, cardiac angioplasty or stenting, unstable angina, New York Heart Association Class II or greater congestive heart failure, or other clinically significant cardiac diseases within 12 months of enrollment • History of symptomatic deep vein thrombosis or pulmonary embolism within 6 months of enrollment • History of autoimmune disease, requiring systemic immunosuppression and/or systemic disease modifying agents within the last 2 years

	• History of anti-CD19 or CAR-T therapy or history of prior randomization in ZUMA-7 • History of Richter's transformation of CLL or PMBCL • Prior CD19 targeted therapy • Treatment with systemic immunostimulatory agents (including but not limited to interferon and IL-2) within 6 weeks or 5 half-lives of the drug, whichever is shorter, prior to the first dose of axicabtagene ciloleucel or SOC • Prior chimeric antigen receptor therapy or other genetically modified T-cell therapy, or prior randomization into ZUMA-7 • History of severe, immediate hypersensitivity reaction attributed to aminoglycosides • Active tuberculosis • History of idiopathic pulmonary fibrosis, organizing pneumonia (eg, bronchiolitis obliterans), drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis per chest computed tomography (CT) scan at screening. History of radiation pneumonitis in the radiation field (fibrosis) is allowed. • Requirement for urgent therapy due to tumor mass effects such as bowel obstruction or blood vessel compression • Treatment with a live, attenuated vaccine within 6 weeks prior to initiation of study treatment, or anticipation of need for such a vaccine during the course of the study • Women of childbearing potential who are pregnant or breastfeeding because of the potentially dangerous effects of chemotherapy on the fetus or infant. Subjects of either sex who are not willing to practice birth control from the time of consent and at least 6 months after the last dose of axicabtagene ciloleucel or SOC chemotherapy • In the investigators judgment, the subject is unlikely to complete all protocol-required study visits or procedures, including follow-up visits, or comply with the study requirements for participation Note: Other protocol defined Inclusion/Exclusion criteria may apply

Ethnicity	
Hispanic/Latino	18
Not Hispanic/Latino	336
Other/Unspecified	5

Race

American Indian/Alaska Native	1
Asian	22
Black/African American	18
Native Hawaiian/Pacific Islander/Indigenous Australian	3
Other/Unspecified	18
White	297

Biomarker Details

Biomarker Name	Biomarker Identifier	Biomarker Official Symbol	Biomarker Role
B and T Lymphocyte Associated	GDBM0011745	BTLA	Monitoring Treatment Response
BCL2 Apoptosis Regulator	GDBM0000168	BCL2	Inclusion criteria
BCL6 Transcription Repressor	GDBM0000171	BCL6	Inclusion criteria
C-c Motif Chemokine Ligand 4	GDBM0001414	CCL4	Predicting Treatment Response
C-C Motif Chemokine Receptor 7	GDBM0000352	CCR7	Predicting Treatment Response
C-reactive protein	GDBM0000385	CRP	Predicting Treatment Response
C-X-C motif chemokine ligand 10	GDBM0000876	CXCL10	Monitoring Treatment Safety
C-X-C Motif Chemokine Ligand 8	GDBM0000852	CXCL8	Predicting Treatment Response
CD19 molecule	GDBM0000270	CD19	Monitoring Treatment Response
CD45RA	GDBM0023271		Predicting Treatment Response
Colony stimulating factor 2	GDBM0000392	CSF2	Monitoring Treatment Safety
Ferritins	GDBM0013350		Monitoring Treatment Safety
Granzyme B	GDBM0000692	GZMB	Monitoring Treatment Safety

Herpesvirus 4, Human	GDBM0021014		Inclusion criteria
Intercellular adhesion molecule 1	GDBM0000792	ICAM1	Monitoring Treatment Safety
Interferon regulatory factor 8	GDBM0000793	IRF8	Monitoring Treatment Response
Interleukin 10	GDBM0000854	IL10	Monitoring Treatment Safety
Interleukin 15	GDBM0000863	IL15	Monitoring Treatment Safety
Interleukin 27	GDBM0002846	IL27	Predicting Treatment Response
Interleukin 6	GDBM0000848	IL6	Monitoring Treatment Safety; Predicting Treatment Response
L-Lactate Dehydrogenase	GDBM0003238		Monitoring Treatment Response; Monitoring Treatment Safety
Membrane spanning 4-domains A1	GDBM0000271	MS4A1	Monitoring Treatment Response
MYC Proto-Oncogene, bHLH Transcription Factor	GDBM0001097	MYC	Inclusion criteria
Protein Tyrosine Phosphatase Receptor Type C	GDBM0001322	PTPRC	Monitoring Treatment Response
TNF receptor superfamily member 17	GDBM0000172	TNFRSF17	Monitoring Treatment Response
Tumor Burden	GDBM0052101		Monitoring Treatment Response

Trial Results	
No. of Subjects Planned	350
No. of Subjects Enrolled	359
No. of Subjects Analyzed	359
Endpoint Classification	Efficacy, Pharmacokinetics, Quality of Life, Safety
End Point Status	Achieved

Efficacy Results	**April 14, 2024** Presented at the 50th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2024), April 14 - 17, 2024, Glasgow, Scotland, United Kingdom The Cost-effectiveness of Axicabtagene Ciloleucel Versus Standard of Care as Second-line Therapy in Patients with Large B-cell Lymphoma in Italy Session: Statistics Abstract No.: P350 Yael Rodriguez-Guadarrama et al.Based on the results reported, GlobalData inferred that 2line axicabtagene ciloleucel treatment of subjects with large B-cell lymphoma was associated with a per patient incremental quality of life gain of 1.92 and incremental costs of €70,577 compared to standard of care resulting in an incremental cost-effectiveness ratio (ICER) of €36,811 per quality of life gained. The better long-term survival of subjects in the axicabtagene ciloleucel arm, more time spent in the event-free state, and the avoidance of subsequent lines of CAR T in the standard of care arm. At a willingness-to-pay of €60,000 per quality-adjusted life years gained, axicabtagene ciloleucel is 69% to be cost-effective. Key drivers of cost-effectiveness included the proportion of axicabtagene ciloleucel subjects receiving subsequent allogeneic stem cell transplantation and post-event utility. https://ebmt2024.abstractserver.com/program/#/details/presentations/1304 **April 05, 2024** Presented at the Annual Meeting of the American Association for Cancer Research (AACR 2024), April 05-10, 2024, San Diego, California, USA Novel Tumor Gene Expression Signatures Predictive of Outcome in Large B Cell Lymphoma Treated with Car T Cell Therapy (Axicabtagene Ciloleucel) Session: LBPO.CL01 - Late-Breaking Research: Clinical Research 1 Abstract No.:LB092 / 3 Tian Y et al.Based on the results presented, GlobalData inferred that high levels(> median) of a favorable 6-transcript GE signature (6-GES) composed of CD19, CD45RA, CCL22, KLRK1, SOX11, and SIGLEC5 positively correlated with EFS (HR: 0.27, 95% CI: 0.16–0.44; P=1.82 x 10-8) and PFS (HR: 0.27, 95% CI: 0.16–0.46; P=1.35 x 10-7) in patients treated with axicabtagene ciloleucel. Conversely, high levels of an unfavorable 17-transcript GE signature (17-GES, CD45RO, BCL2, IL-18R1, TNFSF4 (OX40L), KLRB1 (CD1610, KIR3DL2, ITGB8, DUSP5, GPC4, PSMB5, RPS6KB1, SERPINA9, NBN, GLUD1, ESR1, ARID1A, and SLC16A1) negatively correlated with Axi-cel EFS (HR: 6.19, 95% CI: 3.60–10.65; P=1.51 x 10^{-13}) and PFS (HR: 7.58, 95% CI: 4.16–13.81, P=2.70 x 10^{-14}). The 17-GES signature is consistent with a high level of immune infiltration and inflammation paralleled by the activation of immune-escape mechanisms, such as the upregulation of anti-apoptotic genes. Notably, the 17-GES was elevated at progression after axicabtagene ciloleucel treatment (n=18). These signatures did not associate with outcome to 2nd-line SOC from ZUMA-7, nor with outcome to 1st -line R-CHOP from two online datasets, indicating their predictive rather than prognostic

value.https://www.abstractsonline.com/pp8/#!/20272/presentation/10384

March 07, 2024

Study of Effectiveness of Axicabtagene Ciloleucel Compared to Standard of Care Therapy in Patients With Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)Based on the results published, GlobalData inferred that 359 subjects were analyzed in the study

Arm/Group Title	Axicabtagene Ciloleucel	Standard of Care Therapy
Overall Number of Participants Analyzed	180	179
Median (95% Confidence Interval) Unit of Measure: months		
	8.3 (4.5 to 15.8)	2 (1.6 to 2.8)

https://classic.clinicaltrials.gov/ct2/show/results/NCT03391466

December 21, 2023

U.S. FDA Approves Label Update for Kite's Yescarta CAR T-Cell Therapy to Include Overall Survival DataBased on the results announced by Gilead Sciences, Inc in the press release, GlobalData inferred that study showed statistically significant improvement for Yescarta in OS versus standard of care (SOC) as second-line treatment with curative intent for subjects with relapsed or refractory large B-cell lymphoma (R/R LBCL) within 12 months of completion of first-line therapy. Study demonstrated a 27.4% reduction in the risk of death with Yescarta versus SOC, a relative 38% improvement in OS. With an estimated median follow up of 46.7 months overall, the primary analysis of OS showed a statistically significant improvement in the Yescarta arm compared to the standard therapy arm, despite more than half of subjects (57%) in the SOC arm subsequently receiving cell therapy off protocol. The estimated 39-month OS rates were 55.9% in the Yescarta arm and 46% in the SOC arm.https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/us-fda-approves-label-update-for-kites-yescarta-car-tcell-therapy-to-include-overall-survival-data

December 11, 2023

Analyses of Kites Yescarta CAR T-Cell Therapy Support Curative Potential in Patients With Non-Hodgkin Lymphomas Based on subgroup analysis announced by Gilead Sciences Inc., in the press release, GlobalData inferred the following:

	Yescarta Age	SOC Age 65+	Yescarta Age	SOC Age 70+

	65+		70+	
Median OS (months)	43.5 (95% CI, 20.9-NE)	19.5 (95% CI, 12.3-NE)	24.7 (95% CI, 12.8-NE)	11.2 (95% CI, 6.1-NE)
Median PFS (months)	28.6 (95% CI, 5.1-NE)	5.0 (95% CI, 2.8-7.3)	11.4 (95% CI, 4.1-NE)	2.7 (95% CI, 1.7-5.0)

https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/analyses-of-kites-yescartacar-t-cell-therapy-support-curative-potential-in-patients-with-non-hodgkin-lymphomas

December 09, 2023

Presented at the 65th American Society of Hematology (ASH 2023) Annual Meeting and Exposition, December 09 - 12, 2023, San Diego, California, USA
An Inflammatory Biomarker Signature Reproducibly Predicts CAR-T Treatment Failure in Patients with Aggressive Lymphoma across the Zuma Trials Cohorts
Session: 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Translational Data and Prognostic Factors
Abstract No.: 224 Sandeep Raj et al.Based on the pooled results of NCT02348216 and GDC40002568 presented, GlobalData inferred that assignment to the inflammatory cluster versus. non-inflammatory cluster was significantly associated with an increased risk of not achieving complete response (CR) by day 100 (OR 1.57 (95% CI 1.25 to 2.53)) cohorts. The inflammatory cluster was also significantly associated with inferior overall survival compared with the non-inflammatory cluster HR 1.75 (95% CI 1.39 to 2.59), respectively).https://ash.confex.com/ash/2023/webprogram/Paper173798.html

December 09, 2023

Presented at the 65th American Society of Hematology (ASH 2023) Annual Meeting and Exposition, December 09 - 12, 2023, San Diego, California, USA
Statistical Challenges from Trials of Potentially Curative Treatments: Validation of Cure Assumptions When Analyzing Zuma-7 Follow-up Data of Axi-cel and Standard of Care Therapy
Session: 705.Cellular Immunotherapies: Late Phase and Commercially Available Therapies
Abstract No.: 6899 Anik R Patel et al.Based on the results presented, GlobalData inferred that cure-based and spline models provided the best fit based on the percentage inaccuracy of extrapolations fitted with primary EFS (datacut 1) in comparison to 5-year OS Kaplan-Meier estimates confirmed by primary OS analyses (data cut 2). In the axi-cel treatment arm, the percentage inaccuracy range between 2% and 27%. Based on data cut 1, cure fractions ranged considerably across the mixture cure modeling (MCM) extrapolation forms

considered for both treatment arms (range: 24-54% and 35-49% for axi-cel and SoC, respectively). The range of cure fractions narrowed considerably based on extrapolations performed on the more mature data cut 2 (range: 50-54% and 41-50% for axi-cel and SoC, respectively). Overall, the uncertainty in the estimate of cure fractions based on MCMs was reduced from data cut 1 to data cut 2 for axi-cel vs. SoC, suggesting clinical input is needed to validate early extrapolations using less mature data cuts.
https://ashpublications.org/blood/article/142/Supplement%201/6899/500947/Statistical-Challenges-from-Trials-of-Potentially

December 09, 2023

Presented at the 65th American Society of Hematology (ASH 2023) Annual Meeting and Exposition, December 09 - 12, 2023, San Diego, California, USA
Improved Overall Survival with Axicabtagene Ciloleucel Vs Standard of Care in Second-line Large B-cell Lymphoma among the Elderly: A Subgroup Analysis of ZUMA-7
Session: 627. Aggressive Lymphomas: Clinical and Epidemiological: Poster I
Abstract No.: 1761 Marie Jose Kersten et al.Based on the subgroup analysis results presented, GlobalData inferred that a total of 109 subjects were analyzed in the study. At a median follow-up of 46.6 mo, overall survival (OS) was prolonged in the axicel versus SOC arm in subjects aged ≥65 y (HR, 0.691, 95% CI, 0.401-1.190) and for those ≥70 y (HR, 0.330, 95% CI, 0.135-0.809). Similar results were reported using the piecewise Cox regression model. The median overall survival (OS) for axi-cel and SOC subjects was 43.5 mo (95% CI, 20.9-not estimable (NE)) and 19.6 mo (95% CI, 12.3-NE), respectively, among those aged ≥65 y, and 24.7 mo (95% CI, 12.8-NE) and 11.2 mo (95% CI, 6.1-NE), respectively, among those aged ≥70 y. In the SOC arm, 57% and 52% of subjects received subsequent cellular immunotherapy off protocol in subjects aged ≥65 y and ≥70 y, respectively. Multivariate analyses demonstrated an even greater overall survival (OS) benefit with axi-cel over SOC when adjusting for differences in baseline characteristics in subjects aged ≥65 y (HR, 0.526, 95% CI, 0.266-1.041) and in subjects aged ≥70 y (HR, 0.184, 95% CI, 0.045-0.755).

Meadian Overall survival (OS), (95% CI),mo	**Axi-cel, N=51**	**Standard of care (SOC),N=58**	**Stratified HR(95% CI**
Subjects ≥65 y	43.5(20.9,NE)	19.5(12.3,NE)	0.691(0.401,1.190)
	Axi-cel, N=26	**Standard of care (SOC),N=27**	**Stratified HR(95% CI**
Subjects ≥70 y	24.7(12.8,NE)	11.2(6.1,NE)	0.330(0.135,0.809)

Progression free survival (PFS) assessed by investigator confirmed benefit of axi-

	cel over SOC in subjects aged ≥65 y (HR, 0.406, 95% CI, 0.230-0.715) and in subjects aged ≥70 y (HR, 0.206; 95% CI, 0.078-0.547). The median PFS for axi-cel and SOC subjects was 28.7 mo (95% CI, 5.1-NE) and 5.0 mo (95% CI, 2.8-7.2), respectively, for those aged ≥65 y, and 11.4 mo (95% CI, 4.1-NE) and 2.7 mo (95% CI, 1.7-5.0), respectively, for those aged ≥70 y. Similar associations between product characteristics and outcomes were reported among the elderly and overall populations, including improved OS associated with a greater (>median) proportion of juvenile or stem memory T-cell phenotype cells (CCR7+CD45RA+ T cells) in the axi-cel product among subjects aged ≥65 y (HR, 0.369; 95% CI, 0.138-0.984).https://ash.confex.com/ash/2023/webprogram/Paper173873.html **September 06, 2023** Presented at the 11th Hybrid Annual Meeting of the Society of Hematologic Oncology (SOHO 2023), September 06 - 09, 2023, Houston, Texas, USA Cost-effectiveness of the Chimeric Antigen Receptor (Car) T-cell Treatments, Lisocabtagene Maraleucel (Liso-cel) Versus Axicabtagene Ciloleucel (Axi-cel), as Second-line (2l) Treatment of Large B-cell Lymphoma (Lbcl) Session: Cellular Therapy Abstract No.: CT-107 Matthew Lunning et al. Based on the pooled results of GDC40002568 and GDC30008058 presented, GlobalData inferred that quality-adjusted life-years was gain for lisocabtagene maraleucel over axicabtagene ciloleucel at an additional cost and an incremental cost-effectiveness ratios per quality-adjusted life-years.https://clml-soho2023.elsevierdigitaledition.com/index.html NCT03331198 **June 13, 2023** Presented at the 17th International Conference on Malignant Lymphoma (ICML 2023), June 13 - 17, 2023, Lugano, Switzerland Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard of Care in Relapsed/Refractory Large B-cell Lymphoma Session: Session 3 - Treatment of Aggressive Lymphomas Abstract No: 22 Westin J R et al.Based on the results presented, GlobalData inferred that 359 subjects were enrolled in the study. The axicabtagene ciloleucel(axi-cel) demonstrated a statistically significant improvement in overall survival(OS) over standard of care(SOC) (HR: 0.726, 95% CI: 0.540–0.977, stratified log-rank 1-sided p=0.0168 (efficacy boundary, 0.0249)). Median OS was prolonged with axi-cel versus SOC (not reached versus 31.1 months), 48-months OS estimates were higher with axi-cel (54.6% versus 46.0%). The OS benefit with axi-cel versus SOC was consistent in prespecified key subgroups, including age ≥65 years, primary refractory, early relapse, high-grade B-cell lymphoma, and high second-line age-adjusted IPI and in the SOC arm, 102 (57%) subjects received subsequent cellular immunotherapy off protocol. Prespecified OS sensitivity analyses showed an even greater OS benefit with axi-cel versus

	SOC, with stratified HR of 0.608 (95% CI: 0.449–0.824) by rank-preserving structural failure time model. The progression free survival(PFS) by investigator confirmed benefit of axi-cel over SOC (HR: 0.506, 95% CI: 0.383–0.669), with 48-months PFS estimates of 41.8% versus 24.4%. Improved OS was associated with an increased proportion of a naive T-cell phenotype (CCR7+CD45RA+ T cells, descriptive p<0.05) in the infused product.https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22 **June 13, 2023** Presented at the 17th International Conference on Malignant Lymphoma (ICML 2023), June 13 - 17, 2023, Lugano, Switzerland Circulating Tumor Dna (Ctdna) by Clonoseq to Monitor Residual Disease after Axicabtagene Ciloleucel (Axi-cel) in Large B-cell Lymphoma (Lbcl) Session: Translational Studies, Liquid Biopsy Abstract No: 234 Miles B R et al.Based on the pooled results of NCT03761056, GDC40002568 and GDC30019988 presented, GlobalData inferred that the measurable residual disease(MRD+) detection rate among evaluable pre-infusion samples was only 69% (11/16). At day 50, positive predictive value(PPV) was 100% (7/7) in the standard of acre(SOC) arm, whereas it was only 57% (4/7) in the axicabtagene ciloleucel (axi-cel) arm. The PPV increased over time in the axi-cel arm, reaching 100% by months(Mo) 9 (2/2) and at day 50, negative predictive value (NPV) was 53% (8/15) in the axi-cel arm and 38% (5/13) in the SOC arm. The 47% (9/19) of relapsed subjects on the axi-cel arm had MRD detected at any time and 78% (7/9) had MRD detected prior to or at progression with a median of 35 days prior to progression.https://onlinelibrary.wiley.com/doi/10.1002/hon.3164_234 **June 05, 2023** Kite's Yescarta CAR T-cell Therapy Demonstrates Significantly Longer Overall Survival Versus Standard of Care as Initial Treatment of Relapsed/Refractory Large B-cell LymphomaBased on the results announced by Kite Pharma, in the press release, GlobalData inferred that 27.4% reduction in risk of death, corresponding to a 38% relative improvement in os, despite 57% of subjects subsequently receiving cell therapy off protocolhttps://www.gilead.com/news-and-press/press-room/press-releases/2023/6/kites-yescarta-car-t-cell-therapy-demonstrates-significantly-longer-overall-survival-versus-standard-of-care-as-initial-treatment-of-relapsedrefrac **June 05, 2023** Survival with Axicabtagene Ciloleucel in Large B-Cell Lymphoma Jason R. Westin et al The New England Journal of Medicine, 2023 Based on results reported, Globaldata inferred that a total of 359 subjects were enrolled in the study. The median overall survival was not reached in the axi-cel group and was

	31.1 months in the standard-care group; the estimated 4-year overall survival was 54.6% and 46.0%, respectively (hazard ratio for death, 0.73; 95% confidence interval [CI], 0.54 to 0.98; P=0.03 by stratified two-sided log-rank test). This increased survival with axi-cel was observed in the intention-to-treat population, which included 74% of patients with primary refractory disease and other high-risk features. The median investigator-assessed progression-free survival was 14.7 months in the axi-cel group and 3.7 months in the standard-care group, with estimated 4-year percentages of 41.8% and 24.4%, respectively (hazard ratio, 0.51; 95% CI, 0.38 to 0.67).https://www.nejm.org/doi/full/10.1056/NEJMoa2301665 **June 02, 2023** Presented at the 59th Annual Meeting of American Society of Clinical Oncology (ASCO 2023), June 02 - 06, 2023, Chicago, Illinois, USA Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard-of-care Therapy in Relapsed/refractory Large B-cell Lymphoma Session: Clinical Science Symposium- Moving Cellular Therapy Into Earlier Lines of Treatment in Hematologic Malignancies: Latest Efficacy Data and The Need to Improve Access Abstract No.: LBA107 Jason Westin et al.Based on the results presented, GlobalData inferred that at a median follow-up of 47.2 mo, axi-cel demonstrated a statistically significant improvement in overall survival over SOC (HR [95% CI], 0.726 [0.540-0.977]; stratified log-rank 1-sided P=0.0168 [efficacy boundary, 0.0249]). Median overall survival was longer with axi-cel vs SOC (not reached vs 31.1 mo, respectively); 48-mo overall survival estimates were higher with axi-cel (54.6% vs 46.0%, respectively). Overall survival benefit with axi-cel vs SOC was consistent in prespecified key subgroups, including age ≥65 years, primary refractory, early relapse, high-grade B-cell lymphoma, and high second-line age-adjusted IPI. In the SOC arm, 102 (57%) subjects received subsequent cellular immunotherapy off protocol. Prespecified OS sensitivity analyses, conducted to address the confounding effects of treatment-switching in the SOC arm, showed an even greater OS benefit with axi-cel vs SOC, with stratified HR (95% CI) of 0.608 (0.449-0.824) by RPSFT and 0.633 (0.409-0.981) by IPCW. Progression free survival by investigator confirmed benefit of axi-cel over SOC (HR [95% CI], 0.506 [0.383-0.669]), with 48-mo PFS estimates of 41.8% vs 24.4%, respectively https://meetings.asco.org/abstracts-presentations/220014 **June 02, 2023** Presented at the 59th Annual Meeting of American Society of Clinical Oncology (ASCO 2023), June 02 - 06, 2023, Chicago, Illinois, USA Circulating Tumor DNA (ctDna) by ClonoSEQ to Monitor Residual Disease after Axicabtagene Ciloleucel (Axi-cel) in Large B-cell Lymphoma (LBCL) Session: Hematologic Malignancies—Lymphoma and Chronic Lymphocytic

	Leukemia Abstract No.: 7547 Brodie Miles et al.Based on the pooled results of GDC30019988, NCT03761056, and GDC40002568 presented, GlobalData inferred that at Day 50, positive predictive value (PPV) was 100% (7/7) in the SOC arm, whereas it was only 57% (4/7) in the axi-cel arm. The PPV increased over time in the axi-cel arm, reaching 100% by month 9 (2/2). At Day 50, negative predictive value (NPV) was 53% (8/15) in the axi-cel arm and 38% (5/13) in the SOC arm. Overall, 47% (9/19) of relapsed subjects on the axi-cel arm had minimal residual disease (MRD) detected at any time, of those 9, 78% (7/9) had MRD detected prior to or at progression with a median of 35 days prior to progression.https://meetings.asco.org/abstracts-presentations/220315 **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 Association of Metabolic Tumor Volume (Mtv) and Clinical Outcomes in Second-line Relapsed/Refractory Large B-cell Lymphoma Following Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care (Soc) Therapy in Zuma-7 Session: CAR-based Cellular Therapy – Clinical Abstract No.: P164 Olalekan O Oluwole et al.Based on the results presented, GlobalData inferred that the axicabtagene ciloleucel (Axi-cel) event-free survival (EFS) was superior to standard of care(SOC) for low (≤median) and high (>median) MTV (hazard ratio (HR), 0.423 and HR, 0.417, respectively). Axi-cel EFS trended shorter in subjects with high MTV (HR, 1.441) and EFS was shorter in SOC subjects with high MTV (HR, 1.486).https://ebmt2023.abstractserver.com/program/#/details/presentations/791 **March 21, 2023** KITE'S YESCARTA CAR T-CELL THERAPY DEMONSTRATES A STATISTICALLY SIGNIFICANT IMPROVEMENT IN OVERALL SURVIVAL FOR INITIAL TREATMENT OF RELAPSED/REFRACTORY LARGE B-CELL LYMPHOMABased on the results announced in the press release, GlobalData inferred that the results showed a statistically significant improvement for Yescarta in OS versus historical standard of care in curative setting, Yescarta demonstrated a 2.5-fold increase in subjects who were alive at two years and did not experience cancer progression or require the need for additional cancer treatment (40.5% vs. 16.3%), subjects on the Yescarta arm did not receive additional bridging chemotherapy that could have potentially confounded results.https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract

	February 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 Outcomes of Subsequent Anti-lymphoma Therapies in Patients with Relapsed/Refractory Large B-cell Lymphoma (LBCL) Treated with Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC; ZUMA-7) Session: CAR-based Cellular Therapy – Clinical Abstract No.: P167 Olalekan O Oluwole et al.Based on the results presented, GlobalData inferred that a total of 128 subjects were analyzed in this study. the overall median PFS was 1.7 months and median OS was 8.1 months since 3L treatment initiation, with an objective response rate (ORR) of 25% (CR rate: 13%). For 34 patients who received 3L chemotherapy after initial response to 2L axi-cel, overall median PFS was 1.7 months and median OS was 8.1 months, with an ORR of 32% (CR rate: 18%). The overall median progression free survival was 1.7 months and median overall survival was 8.1 months since third line treatment initiation, with an objective response rate (ORR) of 25% (CR rate: 13%). The overall median PFS was 1.7 months and median OS was 8.1 months, with an ORR of 32% (CR rate: 18%), who received third line chemotherapy after initial response to second line axi-cel. Ten subjects received 3L stem cell transplantation (9 ASCT, 1 allogeneic SCT [alloSCT]) after chemotherapy. The median PFS was 11.5 months versus 1.6 months, and median OS was 17.5 months versus 7.2 months for those who did versus those who did not reach SCT, respectively. The median PFS was 3.5 months, six subjects received subsequent SCT (1 ASCT, 5 alloSCT), 3 (alloSCT) of which immediately followed 3L axi-cel, in the axi-cel arm who received 3L cellular immunotherapy. Six subjects who received SCT, five remained in complete response (CR), one subject had a partial response (PR) after axi-cel retreatment and proceeded to alloSCT with best response of CR, but relapsed 7.3 months after SCT. All six subjects who received SCT were alive. One subject who received 3L axi-cel but no SCT had a CR and was disease-free and alive(8.4 months after retreatment). The median PFS was 6.3 months and median OS was 16.3 months with an ORR of 57% (CR rate: 34%), for subjects who received 3L cellular immunotherapy in SOC arm. Subjects who did not receive cellular immunotherapy had a median PFS and median OS of 1.9 months and 9.5 months, respectively.https://ebmt2023.abstractserver.com/program/#/details/presentations/790 **February 15, 2023** Presented at the 2023 Transplantation & Cellular Therapy (TCT 2023) Meetings, February 15 - 19, 2023, Orlando, Florida, USA Outcomes of Subsequent Anti-Lymphoma Therapies in Patients (Pts) with Large B-Cell Lymphoma (LBCL) Treated with Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC) in the Second-Line (2L) Zuma-7 Study Session: Poster Session: Lymphoma/Cll - Clinical

	Abstract No.: 496 Armin Ghobadi et al.Based on the results presented, GlobalData inferred that ten subjects received SCT in 3L after chemotherapy (9 ASCT, 1 allogeneic SCT [alloSCT]), but it is unknown how many subjects were intended for SCT. Median PFS was 11.5 months versus 1.6 months, and median OS was 17.5 months versus 7.2 months for those who did versus those who did not reach SCT, respectively. Subjects who did not receive cellular immunotherapy had a median PFS and median OS of 1.9 months and 9.5 months, respectively.https://astct-29-s2.elsevierdigitaledition.com/ **February 15, 2023** Presented at the 2023 Transplantation & Cellular Therapy (TCT 2023) Meetings, February 15 - 19, 2023, Orlando, Florida, USA Association of Metabolic Tumor Volume (MTV) and Clinical Outcomes in Second-Line (2L) Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Following Axicabtagene Ciloleucel (Axi-Cel) Versus Standard-of-Care (SOC) Therapy in Zuma-7 Session: Poster Session: Immune Reconstitution and Immunobiology Abstract No.: 497 Frederick L Locke et al.Based on the results presented, GlobalData inferred that in axi-cel participants, the median metabolic tumor volume was 228.1 mL (range, 2.3-16,669.3); in SOC subjects, it was 231.9 mL (range, 0.04-2811.2); and overall, it was 230.2 mL (range, 0.04-16,669.3). Those with elevated LDH (n=185; >median) had a greater median metabolic tumor volume than those with normal LDH (n=156; median) (371.2 mL [range, 2.3-16,669.3] vs 123.9 mL [range, 0-3712.8]). SPD (n=308; Spearman correlation, 0.523) and LDH (n=341; Spearman correlation, 0.452) were both positively correlated with metabolic tumor volume. For low (median hazard ratio [HR], 0.423) and high (median > hazard ratio [HR], 0.417) MTV, axi-cel event-free survival (EFS) was superior to SOC. Event free survival was shorter in SOC subjects with high metabolic tumor volume and Axi-cel event free survival trended shorter in pts with high MTV (HR, 1.441). (HR, 1.486) https://astct-29-s2.elsevierdigitaledition.com/ **December 11, 2022** Presented at the 64th Hybrid American Society of Hematology (ASH 2022) Annual Meeting and Exposition, December 10 - 13, 2022, New Orleans, Louisiana, USA Outcomes of Subsequent Anti-Lymphoma Therapies in Patients (Pts) With Large B-Cell Lymphoma (LBCL) Treated With Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC) in the Second-Line (2L) ZUMA-7 Study Session: 705. Cellular Immunotherapies: Results from CD19-Directed CAR T in treating Aggressive B-cell Lymphomas Abstract No.: 659 Armin Ghobadi et al.Based on the results presented, GlobalData inferred that the subjects who received third-line (3L) chemotherapy, overall median progression-free survival (PFS) was 1.7 months (95% CI, 1.4-2.0) and median overall survival (OS) was 8.1 months (95% CI, 5.8-11.5) since 3L

	treatment initiation, with an objective response rate (ORR) of 25% (CR rate: 13%). For 34 subjects who received 3L chemotherapy after initial response to second-line (2L) axi-cel, overall median progression-free survival (PFS) was 1.7 months (95% CI, 1.4-2.4) and median OS was 8.1 months (95% CI, 6.8-11.9), with an ORR of 32% (CR rate: 18%). Median progression-free survival (PFS) was 11.5 months (95% CI, 2.4-not evaluable (NE)) versus 1.6 months (95% CI, 1.2-1.8), and median OS was 17.5 months (95% CI, 2.4-NE) vs 7.2 months (95% CI, 4.8-9.1) for those who did vs those who did not reach SCT, respectively. Of eight subjects in the axi-cel arm who received third-line (3L) cellular immunotherapy, median PFS was 3.5 months (95% CI, 1.1-NE); six received subsequent SCT (1 ASCT, 5 alloSCT) in any line, three (alloSCT) of which immediately followed 3L axi-cel. Of six subjects who received SCT, 5 remained in CR; 1 subject had a PR after axi-cel retreatment and proceeded to alloSCT with best response of CR, but relapsed 7.3 months after SCT. All six subjects who received stem cell transplant (SCT) were alive (median follow-up since 3L treatment initiation: 24.4 months). Of two subjects who received 3L axi-cel but did not receive SCT, 1 had disease progression after 3L axi-cel and died 8.7 months after retreatment, and 1 had a CR after 3L axi-cel and was disease-free and alive (8.4 months after retreatment). In the standard-of-care (SOC) arm, 127 of 179 randomized subjects required 3L subsequent therapy; of these, 68 subjects received 3L cellular immunotherapy. For pts who received 3L cellular immunotherapy, median progression-free survival (PFS) was 6.3 months (95% CI, 3.4-16.3) and median OS was 16.3 months (95% CI, 8.7-NE), compared with median PFS and median overall survival (OS) of 1.9 months (95% CI, 1.1-2.7) and 9.5 months (95% CI, 6.6-15.4), respectively, for those who did not receive cellular immunotherapy. Of 68 subjects who received 3L cellular immunotherapy and were evaluated for response, objective response rate (ORR) was 57% (CR rate: 34%). Outcomes for subjects who received subsequent 3L cellular therapy were numerically inferior to those who received 2L cellular therapy. These findings help inform subsequent treatment choices after failure of 2L therapy for R/R LBCL. https://ash.confex.com/ash/2022/webprogram/Paper158303.html **December 11, 2022** Body of Evidence Grows From ZUMA-7 Study Supporting Initial Treatment With Kite's Yescarta CAR T-Cell Therapy for Patients With Relapsed or Refractory Large B-Cell LymphomaBased on the results announced by Kite, in the press release, GlobalData among yescarta subjects who received third-line (3L) cellular immunotherapy (n=8), median PFS was 3.5 months (95% CI, 1.1-not evaluable), and six subjects went on to receive subsequent stem cell transplant, with all six alive (median follow-up since 3L treatment initiation: 24.4 months). In an analysis from ZUMA-7 of the association of metabolic tumor volume (MTV) and clinical outcomes, event-free survival (EFS) was superior for yescarta compared to SOC for subjects with high and low MTV (HR, 0.417 and 0.423, respectively; descriptive P<0.05 for both). Event-free survival (EFS) trended shorter in yescarta subjects with high MTV (HR, 1.441 [95% CI, 0.978-

	2.124]) and EFS was shorter in SOC subjects with high MTV (HR, 1.486 [95% CI, 1.055-2.093]). Similarly, progression-free survival (PFS) with yescarta was superior to SOC for both low and high MTV (HR, 0.504 (95% CI, 0.328-0.776) and HR, 0.523 (95% CI, 0.357-0.765), respectively). ZUMA-7 demonstrated that axi-cel is superior to standard of care across common prognostic subgroups, including tumor burden.https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/body-of-evidence-grows-from-zuma-7-study-supporting-initial-treatment-with-kites-yescarta-car-t-cell-therapy-for-patients-with-relapsed-or-refractor **December 10, 2022** Presented at the 64th Hybrid American Society of Hematology (ASH 2022) Annual Meeting and Exposition, December 10 - 13, 2022, New Orleans, Louisiana, USA Association of Metabolic Tumor Volume (MTV) and Clinical Outcomes in Second-Line (2L) Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Following Axicabtagene Ciloleucel (Axi-Cel) Versus Standard-of-Care (SOC) Therapy in ZUMA-7 Session: 705. Cellular Immunotherapies: Novel Predictors of Response or Toxicity to Cellular Therapies Abstract No.: 259 Frederick L. Locke et al.Based on the results presented, GlobalData inferred that progression-free survival (PFS) was shorter in both axi-cel and SOC subjects with high metabolic tumor volume (MTV) (HR, 1.644 (95% CI, 1.090-2.480) and HR, 1.635 (95% CI, 1.098-2.433), respectively). This analysis is the first to examine MTV in a large, randomized, prospective R/R LBCL study. Similar to associations of efficacy with sum of product diameters (SPD) and lactate dehydrogenase (LDH) previously observed in 2L LBCL, high MTV was associated with superior outcomes in subjects treated with axi-cel versus SOC. While tumor burden per sum of product diameters (SPD) did not seem to impact axi-cel outcomes in ZUMA-7, high MTV was associated with poorer outcomes with axi-cel versus low MTV. This suggests that MTV is a more accurate and sensitive measure of TB versus SPD. Nevertheless, axi-cel was superior to SOC irrespective of MTV subgroup, including among subjects in the high MTV subgroup.https://ash.confex.com/ash/2022/webprogram/Paper158492.html **December 10, 2022** Presented at the 64th Hybrid American Society of Hematology (ASH 2022) Annual Meeting and Exposition, December 10 - 13, 2022, New Orleans, Louisiana, USA Matching-adjusted Indirect Comparison (MAIC) of Lisocabtagene Maraleucel (Liso-cel) Versus Axicabtagene Ciloleucel (Axi-cel) for Second-line (2L) Treatment of Patients (Pt) with Refractory/Early Relapsed (R/R) Large B-cell Lymphoma (LBCL) Session: 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster I

	Abstract No.: 4673 Jeremy S Abramson et al.Based on the pooled results of and GDC30008058 and GDC40002568 presented, GlobalData inferred that in matching-adjusted indirect comparison (MAIC) of subjects treated with lisocabtagene maraleucel (liso-cel) vs subjects treated with axicabtagene ciloleucel (axi-cel), unmatched and unadjusted comparisons showed no differences in median (95% CI) event free survival for liso-cel (10.1 months [6.1?not reached]) vs axi-cel (8.3 months [4.5?15.8]; HR, 0.94 [0.58?1.52]). MAIC primary scenario efficacy results (event free survival, overall response rate, complete response rate) for matched subjects between liso-cel treated subjects and axi-cel treated subjects showed no differences. Sensitivity scenario comparisons that included additional adjustment factors led to similar results. https://ash.confex.com/ash/2022/webprogram/Paper160216.html https://ashpublications.org/blood/article/140/Supplement%201/4655/490968/Matching-Adjusted-Indirect-Comparison-MAIC-of?searchresult=1 **June 11, 2022** Presented at the 27th *Hybrid* Annual Congress of the European Hematology Association (EHA 2022), June 09 - 12, 2022, Vienna, Austria Clinical and Patient-Reported Outcomes in a Phase 3 Study of Axicabtagene Ciloleucel (Axi-Cel) vs Standard-of-Care in Elderly Patients With Relapsed/Refractory Large B-Cell Lymphoma (Zuma-7) Session: Oral Presentation: Aggressive Lymphoma - CART Abstract No.: S211 Anna Sureda et al.Based on the results presented, GlobalData inferred that 109 subjects were analyzed in the study. Event-free survival was superior with axicabtagene ciloleucel vs standard-of-care (HR, 0.276, P<0.0001), with higher complete response rates, 75% vs 33%. In the quality-of-life analysis set, there were statistically significant and clinically meaningful differences in mean change of scores from baseline at day 100 favoring axicabtagene ciloleucel for EORTC QLQ-C30 Global Health (P<0.0001) and Physical Functioning (P=0.0019) and EQ-5D-5L visual analog scale (VAS)(P<0.0001). For all 3 domains, scores also favored (P<0.05) axicabtagene ciloleucel over standard-of-care at day 150. The mean estimated scores numerically returned to or exceeded baseline scores earlier in the axicabtagene ciloleucel arm, by day 150, but never equaled or exceeded baseline scores by month 15 in the standard-of-care arm.https://library.ehaweb.org/eha/2022/eha2022-congress/357075/anna.sureda.clinical.and.patient-reported.outcomes.in.a.phase.3.study.of.html?f=menu%3D6%2Abrowseby%3D8%2Asortby%3D2%2Amedia%3D3%2Ace_id%3D2233%2Aot_id%3D26858%2Amarker%3D1751 **June 04, 2022**

	Presented at the 58th Annual Meeting of American Society of Clinical Oncology (ASCO 2022), June 03 - 07, 2022, Chicago, Illinois, USA Clinical and Patient (Pt)-reported Outcomes (PROs) in a Phase 3, Randomized, Open-label Study Evaluating Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care (SOC) Therapy in Elderly Pts with Relapsed/Refractory (R/R) Large B-cell Lymphoma (LBCL; Zuma-7) Session: Poster Session- Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia Abstract No.: 7548 Jason Westin et al.Based on the results presented, GlobalData inferred that a total of 109 subjects were analyzed in the study. Event-free survival (EFS) was superior with axi-cel versus standard-of-care (SOC) (HR, 0.276, P< 0.0001), with higher CR rates (75% vs 33%). In the QoL analysis set comprising 46 axi-cel and 42 SOC subjects, there were statistically significant and clinically meaningful differences in mean change of scores from BL at D100 favoring axi-cel for EORTC QLQ-C30 GH (P<0.0001) and PF (P=0.0019) and EQ-5D-5L VAS (P<0.0001). For all 3 domains, scores also favored (P<0.05) axi-cel over SOC at D150. The mean estimated scores numerically returned to or exceeded BL scores earlier in the axi-cel arm (by D150) but never equaled or exceed BL scores by M15 in the SOC arm.https://meetings.asco.org/abstracts-presentations/209923 **June 04, 2022** Presented at the 58th Annual Meeting of American Society of Clinical Oncology (ASCO 2022), June 03 - 07, 2022, Chicago, Illinois, USA Association of Pretreatment (Pretx) Tumor Characteristics and Clinical Outcomes Following Second-line (2l) Axicabtagene Ciloleucel (Axi-cel) Versus Standard of Care (SOC) in Patients (Pts) with Relapsed/Refractory (R/R) Large B-cell Lymphoma (LBCL) Session: Poster Session- Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia Abstract No.: 7565 Frederick L Locke et al.Based on the results presented, GlobalData inferred that Axi-cel Event-free survival (EFS) was superior to standard-of-care (SOC) for both high and low TB (HR, 0.29 and 0.49, respectively; P<.001 for both) and elevated and nonelevated LDH (HR, 0.32 and 0.5, respectively; P<.001 for both). EFS in axi-cel subjects was not associated with pretreatment (Pretx) TB (HR, 1.01 [95% CI, 0.88-1.16]; P=.89) or LDH (HR, 0.98 [95% CI, 0.74-1.29]; P=.86), but was worse in SOC subjects with higher preTx TB (HR, 1.17 [95% CI, 1.03-1.32]; P=.01) or higher LDH (HR, 1.29 [95% CI, 1.02-1.63], P =.03). PreTx TB was lower in SOC subjects with ongoing response vs nonresponders and subjects who relapsed (P=.07), but not in axi-cel subjects (P=.99). Non-germinal center B-cell (GCB) cell-of-origin subtypes is a poor prognostic factor for EFS in SOC (EFS was significantly worse in SOC subjects with non-GCB vs GCB; HR, 1.82 [95% CI, 1.12-2.96]; P=.02) but not in axi-cel. In IO360 analysis, gene expression of B-cell lineage antigens (CD19, CD20, BCMA) and markers highly expressed by tumor cells

	(CD45RA, IRF8, BTLA) positively associated with objective and durable responses to axi-cel. While axi-cel remained superior to SOC with high (> median) or low CD19 expression level, the probability of an ongoing response increased with a higher CD19 H-score. PreTx TME IS15 and IS21 scores were generally higher in 2L vs 3L.https://meetings.asco.org/abstracts-presentations/210240 **June 04, 2022** Sub-analyses of Landmark ZUMA-7 Trial Reinforce Yescarta CAR T-cell Therapy Superiority Over Standard of Care (SOC) as Initial Treatment for Patients With Relapsed or Refractory Large B-cell Lymphoma (LBCL)Based on the results reported in the press release, GlobalData inferred that the event-free survival (EFS) demonstrated that Yescarta (n=51) was superior to SOC (salvage chemoimmunotherapy followed by high-dose chemotherapy and stem cell transplant in those who respond; n=58; Hazard Ratio [HR], 0.276; descriptive P<0.0001), with over eight-fold greater median EFS (21.5 months vs 2.5 months) and over three-fold greater estimated 24-month EFS rate (47.8% vs 15.1%) in sub-analysis of subjects aged 65 and older. Objective response rate (ORR) was higher with Yescarta vs. SOC (88% vs 52%; Odds Ratio: 8.81; descriptive P<0.0001). Complete response (CR) rates in the Yescarta group were over double that of the SOC group (75% vs 33%). Overall survival (OS), evaluated as a preplanned interim analysis, was prolonged in the Yescarta arm compared with the SOC arm (HR, 0.517). Fifty-seven percent of subjects in the SOC arm received subsequent cellular immunotherapy (off protocol). Yescarta showed meaningful improvement in quality of life (QoL) over SOC with faster recovery to pre-treatment quality of life among subjects 65 years of age or older. Among those evaluable for the PRO, Yescarta (n=46) showed clinically meaningful differences in QoL at Day 100 compared to subjects receiving SOC (n=42) for three prespecified PRO domains (European Organisation for Research and Treatment of Cancer [EORTC] Quality of Life Questionnaire [QLQ]-C30 Global Health Status/QOL, EORTC QLQ-C30 Physical Functioning, and EQ-5D-5L visual analog scale [VAS]). For all three domains, scores continued to favor Yescarta over SOC at Day 150 (descriptive P<0.05). In analysis of pre-treatment tumor characteristics including tumor burden and LDH, EFS was superior for Yescarta compared to SOC for subjects with high and low pre-treatment tumor burden (HR, 0.29 and 0.49, respectively; descriptive P<0.001 for both) and elevated and non-elevated LDH (HR, 0.32 and 0.5, respectively; descriptive P<0.001 for both). EFS in Yescarta subjects was not significantly different for subjects with high or low pre-treatment tumor burden (HR, 0.92; descriptive P=0.68) or elevated and non-elevated LDH (HR, 1.11; descriptive P=0.61), but was worse in subjects who received SOC with high pre-treatment tumor burden (HR, 1.51; descriptive P=0.02) or elevated LDH (HR, 1.56; descriptive P=0.01). Durable responses with Yescarta were greatest in tumors with prominent B-cell features, but were superior to SOC regardless of

	these features.https://www.businesswire.com/news/home/20220604005006/en/Sub-analyses-of-Landmark-ZUMA-7-Trial-Reinforce-Yescarta%C2%AE-CAR-T-cell-Therapy-Superiority-Over-Standard-of-Care-SOC-as-Initial-Treatment-for-Patients-With-Relapsed-or-Refractory-Large-B-cell-Lymphoma-LBCL **June 04, 2022** Presented at the 58th Annual Meeting of American Society of Clinical Oncology (ASCO 2022), June 03 - 07, 2022, Chicago, Illinois, USA Quality-adjusted Time Without Symptoms or Toxicities (Q-TWiST) Analysis of ZUMA-7, a Randomized Controlled Trial of Axicabtagene Ciloleucel Versus Standard of Care for Second-line Large B-cell Lymphoma Session: Poster session-Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia Abstract No.: 7555 Marie Jose Kersten et al.Based on the results presented, GlobalData inferred that for the ITT cohort(n=359), mean time spent in TOX and TWiST was significantly longer for the axi-cel cohort compared to SOC, and mean time spent in REL was significantly shorter for axi-cel. Using the base case, quality-adjusted survival was significantly longer for axi-cel by 3.7m, representing a 21.9% relative gain. In threshold analyses, the difference in Q-TWiST ranged from 1.2m (u(TOX)=0, u(REL)=1) to 6.2m (u(TOX)=1, u(REL)=0) in favor of axi-cel. Q-TWiST gains favored axi-cel across all subgroup analyses. Q-TWiST gains from axi-cel increased with longer follow-up.https://meetings.asco.org/abstracts-presentations/209948 **May 16, 2022** Presented at the 25th Hybrid Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT 2022), May 16 - 19, 2022, Washington, D.C, USA Primary Analysis of ZUMA7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-Cel) versus StandardofCare (SOC) Therapy in Patients (Pts) with Relapsed/ Refractory (R/R) Large B-Cell Lymphoma (LBCL) Session: Cancer - Targeted Gene and Cell Therapy II Abstract No.: 1113 Armin Ghobadi et al.Based on the results presented, GlobalData inferred that overall, 74% of subjects had primary refractory disease and 46% had high 2L age-adjusted IPI (2-3). While 94% of axicabtagene ciloleucel subjects were infused, only 36% of standard of care subjects reached high-dose chemotherapy with autologous stem cell transplant. The primary endpoint of EFS was met (HR (hazard ratio) 0.398; P<0.0001), at 24.9-months median follow-up, median EFS was significantly longer with axicabtagene ciloleucel vs standard of care (8.3 vs 2 mo); 24-months EFS Kaplan-Meier estimates were 41% vs 16%. Objective response rate and complete response (CR) rates were higher with axicabtagene ciloleucel vs standard of care (ORR: 83% vs 50%; P<0.0001; CR: 65% vs 32%). Median overall survival, evaluated as an interim analysis, was not reached for axicabtagene ciloleucel vs 25.7 mo for

	standard of care (hazard ratio 0.708; P is 0.0159). In the standard of care cohort, 100 (56%) subjects received cellular immunotherapy off protocol as subsequent therapy.https://www.cell.com/molecular-therapy-family/molecular-therapy/pdf/S1525-0016(22)00246-5.pdf **April 27, 2022** FDA Approves Axicabtagene Ciloleucel for Second-Line Treatment of Large B-Cell LymphomaBased on the results reported in the press release, GlobalData inferred that 359 subjects were randomised in the study. The estimated 18-month EFS rate was 17.0% (95% CI 11.8, 23.0) in the standard therapy arm. 35% subejctsof standard therapy received standard therapy on-protocol autologous HSCT; lack of response to chemotherapy was the most common reason for not receiving HSCT.https://www.esmo.org/oncology-news/fda-approves-axicabtagene-ciloleucel-for-second-line-treatment-of-large-b-cell-lymphoma **April 26, 2022** Presented at The 2022 Transplantation & Cellular Therapy (TCT 2022) Meetings, April 23 - 26, 2022, Salt Lake City, Utah, USA Cost-Effectiveness of Axicabtagene Ciloleucel As Second-Line Therapy for Patients Large B-Cell Lymphoma (LBCL) in the United States Session: Late Breaking Abstracts Abstract No.: LBA2 Miguel Angel Perales et al.Based on the results presented, GlobalData inferred that the model projected median overall survival (OS) was 59 months for the axicabtagene ciloleucel (Axi-Cel) arm and 25 months for the standard-of-care (SOC) arm. Incremental LY and QALY gains for axi-cel versus SoC were 1.34 and 1.37, respectively. The discounted incremental cost for axi-cel versus SoC was $119,055. Despite the higher upfront treatment costs with axi-cel, the high cost of 3L treatment in the SoC arm due to chimeric antigen receptor T-cell (CAR T) use was one key cost category that reduced the difference in cost between the two arms (axi-cel: $144,281; SoC: $373,162; difference: -$228,341). Incremental costs and QALY differences resulted in an incremental cost-effectiveness ratio (ICER) of $87,026/QALY versus SoC. At a willingness-to-pay threshold of $150,000/QALY, probabilistic sensitivity analysis demonstrated that axi-cel has a 72% probability of being cost-effective versus SoC.https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/20530 **April 26, 2022** Presented at The 2022 Transplantation & Cellular Therapy (TCT 2022) Meetings, April 23 - 26, 2022, Salt Lake City, Utah, USA Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-Cel) Versus Standard of Care (SOC) Therapy in Patients with Relapsed/Refractory Large B-Cell Lymphoma Session: Tandem Meetings Best Abstracts

	Abstract No.: 1 Frederick L. Locke et al.Based on the results presented, GlobalData inferred that event-free survival was met(HR: 0.398; 95% CI: 0.308-0.514, P<.0001) and at 24.9 months median follow-up, median event-free survival was significantly longer with axi-cel versus SOC(8.3 months(95% CI: 4.5-15.8) versus 2 months for axi-cel and SOC subjects, respectively), 24-month event-free survival Kaplan-Meier estimates were 41% versus 16%. Objective response rate and complete response rates were higher with axi-cel versus SOC(ORR: 83% versus 50%, odds ratio: 5.31(95% CI: 3.1-8.9, P<.0001), CR: 65% versus 32%). Median overall survival, evaluated as an interim analysis, was not reached for axi-cel versus 35.1 months for SOC(HR: 0.730; P=.027). In the SOC cohort, 100(56%) subjects received cellular immunotherapy off protocol as subsequent therapy. Axi-cel showed superiority over standard of care with >4-fold greater median event free survival, 2.5-fold greater 2-year event free survival, double the complete response rate, and nearly three times the number of subjects receiving definitive therapy.https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19266 **April 25, 2022** Presented at The 2022 Transplantation & Cellular Therapy (TCT 2022) Meetings, April 23 - 26, 2022, Salt Lake City, Utah, USA Patient-reported Outcomes (PROS) in Zuma-7, a Phase 3, Randomized, Open-label Study Evaluating the Efficacy of Axicabtagene Ciloleucel (AXI-CEL) Versus Standard-of-care (SOC) Therapy in Patients with Relapsed/Refractory Large B-cell Lymphoma (LBCL) Session: Poster Session: CAR-T - Clinical: Regulatory, Efficacy, Persistence Abstract No.: 234 Julio Chavez et al. Based on the results presented, GlobalData inferred that there was a statistically significant (P<.0001) and clinically meaningful difference in mean change of scores from BL at D100 in favor of axi-cel on all prespecified PRO domains. The scores significantly favored axi-cel over standard-of-care (SOC) for EORTC QLQ-C30 Global Health Status/QoL (P=.0124) and EQ-5D-5L VAS (P=.0004) at D150. The mean estimated scores for the axi-cel arm had numerically returned to or exceeded scores at BL by D150 versus on or after M9 for the SOC arm. The attrition in the QoL analysis set was substantial, particularly in the SOC arm. The treatment with axicabtagene ciloleucel (axi-cel) resulted in clinically meaningful improvement in QoL over SOC at D100 as measured by multiple validated PRO instruments.https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19351 **April 11, 2022** Presented at the 113th Annual Meeting of the American Association for Cancer Research (AACR 2022), April 08 - 13, 2022, New Orleans, Louisiana, USA Gender bias in the association of pre-treatment cytokine signatures with response and survival in B cell lymphoma patients treated with anti-CD19 CAR T-cell therapy

	Session: PO.CL11.07 - Biomarkers Predictive of Therapeutic Benefit 2 Abstract No.: 1262 / 9 Manishkumar S. Patel et al.Based on the results reported, GlobalData inferred that 42 subjects (62% male) were analyzed in the study. Male non-responders (stable/progressive disease) had significantly higher baseline levels of IL-6, IL-8, IL-1RA, MIP-1α, GM-CSF and CRP compared to responders (complete/partial response). Higher levels of IL-6, IL-8, IL-27, and CRP were significantly associated with poor overall survival (OS), and IL-6, IL-8, MIP-1β, and CRP with poor progression-free survival (PFS) in male patients. Baseline metabolic tumor volume (MTV) and lactate dehydrogenase (LDH) levels were also significantly higher in male patients with poor OS and PFS. Finally, baseline IL-8 and CRP were significantly associated with baseline MTV and LDH levels in male patients.https://www.abstractsonline.com/pp8/#!/10517/presentation/12678 **April 10, 2022** Presented at the 113th Annual Meeting of the American Association for Cancer Research (AACR 2022), April 08 - 13, 2022, New Orleans, Louisiana, USA Product attributes of axicabtagene ciloleucel (axi-cel) that associate differentially with efficacy and toxicity in second-line large B-cell lymphoma Session: CTPL01 - Clinical Trials of Cellular Immunotherapies Abstract No.: CT004 Jason R Westin et al. Based on the results presented, GlobalData inferred that chimeric antigen receptor T-cell peak and AUC_{0-28} correlated with higher objective response rate (P is.0224 and .0054, respectively) and increased Grade ≥3 neurologic events (P is.0006) but not with durability of response (P is 4894). Rapid transient increases in serum analytes, including granzyme B, ferritin, interleukin-6, interleukin-10, CXCL-10, interleukin-15, ICAM-1, and GM-CSF, occurred early (median peak ≤7 days) and were associated with increased grade ≥3 neurologic events and grade≥3 cytokine release syndrome (P<.05). Infusion products richer in naive-like T cells expressing CD27 and CD28 associated with increased event free survival, objective response rate, and complete response (P<.05). In contrast, infusion products richer in differentiated T cells (CCR7-) and with lower % of CCR7+CD45RA+ T cells associated with higher post infusion peak levels and AUC_{0-28} of several proinflammatory and immunomodulatory serum analytes. Increased rates of grade ≥3 neurologic events were found in subjects who received axicabtagene ciloleucel richer in CCR7- T cells (above median: 30% vs below median: 10%). Similarly, a trend of higher rates of grade≥3 neurologic events and cytokine release syndrome were observed in subjects who received axicabtagene ciloleucel that secreted higher levels of inferone gamma in co-culture with CD19-expressing targets.https://www.abstractsonline.com/pp8/#!/10517/presentation/20146 **March 23, 2022**

	Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel(axi-Cel) Versus Standard of Care(soc) Therapy in Patients With Relapsed/Refractory Large B-Cell Lymphoma Session: OS13 Oral session 13: CAR-T II Abstract No.: OS13-06 Tom van Meerten et al.Based on the results presented, GlobalData inferred that a total of 359 subjects were randomized in the study. The primary endpoint of event-free survival (EFS) was met (hazard ratio (HR): 0.398; 95% CI: 0.308-0.514; P<.0001). At 24.9 months median follow-up, median event-free survival (EFS) was significantly longer with axi-cel versus standard of care (SOC) (8.3 months [95% CI: 4.5-15.8] versus two months for axi-cel and standard of care (SOC) subjects, respectively).https://ebmt2022.abstractserver.com/program/#/details/presentations/855 **March 22, 2022** Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Superiority of Axicabtagene Ciloleucel (Axi-cel) in Second-line (2l) Large B-cell Lymphoma (Lbcl) in the Elderly Session: OS08 Oral session 8: CAR-T I Abstract No.: OS08-05 Tom van Meerten et al.Based on the results presented, GlobalData inferred that the multivariate analyses showed the similar EFS results when adjusting for differences in baseline characteristics (HR, 0.232, P<0.0001). Axi-cel had a higher overall response rate and complete response rate than standard of care (ORR: 88% vs 52% ; CR: 75% vs 33% , respectively).https://ebmt2022.abstractserver.com/program/#/details/presentations/819 **March 19, 2022** Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Patient-reported Outcomes in Zuma-7, a Phase 3, Randomized, Open-label Study Evaluating the Efficacy of Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care Therapy in Relapsed/Refractory Large B-cell Lymphoma Session: CAR-based Cellular Therapy-Clinical, Abstract No.: P104 Mahmoud Elsawy et al.Based on the results presented, GlobalData inferred that there was a statistically significant(P<.0001) and clinically meaningful difference in mean change of scores from baseline at Day 100 in favor of axicel on all prespecified PRO domains. Sensitivity analyses showed similar results with retained significance at Day 100 and scores significantly favored axi-cel over SOC for EORTC QLQ-C30 Global Health Status/QoL(P=.0124) and EQ-5D-5L VAS(P=.0004) at Day 150. For prespecified

endpoints, the mean estimated scores for the axi-cel arm had numerically returned to or exceeded scores at baseline by Day 150 versus on or after Month 9 for the SOC arm. After Month 9, attrition (eg, an EFS event) in the QoL analysis set was substantial, particularly in the SOC arm. Analyses of additional PRO endpoints demonstrated similar trends.https://ebmt2022.abstractserver.com/program/#/details/presentations/805

March 19, 2022

Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Cost-effectiveness of Axicabtagene Ciloleucel as Second-line Therapy for Patients Large B-cell Lymphoma (Lbcl) in the United States
Session: CAR-based Cellular Therapy – Clinical
Abstract No.: P090 Patrick Johnston et al.Based on the results presented, GlobalData inferred that, incremental LY and quality gains for axicel versus salvage chemoimmunotherapy were 1.34 and 1.37, respectively.
Findings:

	LYs	**Costs**	**QALYs**
Axicel	9.14	$683,698	7.08
SoC	7.8	$564,642	5.71
Incremental	1.34	$119,055	1.37
Incremental cost effectiveness ratio, axicel vs. SoC			$87,026

https://ebmt2022.abstractserver.com/program/#/details/presentations/1024

December 12, 2021

Presented at the 63rd Virtual American Society of Hematology (ASH 2021) Annual Meeting and Exposition, December 11 - 14, 2021, Atlanta, Georgia, USA Primary Analysis of Zuma-7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care Therapy in Patients with Relapsed/Refractory Large B-cell Lymphoma
Session: Plenary Scientific Sessiona
Abstract No.: 2 Frederick L Locke et al.Based on the results presented, GlobalData inferred that a total of 359 subjects were analyzed in the study.

The primary endpoint of event free survival was met (HR: 0.398; P<.0001). At 24.9 mo median follow-up, median EFS was significantly longer with axi-cel vs standard of care (8.3 mo [95% CI: 4.5–15.8] vs 2 mo [95% CI: 1.6–2.8],

	respectively), and Kaplan-Meier estimates of the 24-mo EFS rates were significantly higher with axi-cel (41% vs 16%). Among randomized subjects, ORR and CR rates were higher with axi-cel vs standard of care (ORR: 83% vs 50%, odds ratio: 5.31 [95% CI: 3.1–8.9; P<.0001]; CR: 65% vs 32%). Median overall survival (OS), evaluated as a preplanned interim analysis, favored axi-cel vs SOC, although it did not meet statistical significance (not reached vs 35.1 mo, respectively; HR: 0.730; P=.027). In the standard of care arm, 100 (56%) received commercially available or investigational CAR T-cell therapy off protocol as subsequent treatment. Median peak CAR T-cell level was 25.8 cells/μL; median time to peak was 7 d after infusion. Axi-cel showed superiority over standard of care with >4-fold greater median EFS, 2.5-fold greater EFS at 2 y, double the CR rate, and more than double the percentage of pts receiving definitive treatment. https://ash.confex.com/ash/2021/webprogram/Paper148039.html **December 12, 2021** Presented at the 63rd Virtual American Society of Hematology (ASH 2021) Annual Meeting and Exposition, December 11 - 14, 2021, Atlanta, Georgia, USA Patient-Reported Outcomes in a Phase 3, Randomized, Open-Label Study Evaluating the Efficacy of Axicabtagene Ciloleucel (Axi-Cel) Versus Standard of Care Therapy in Patients with Relapsed/Refractory Large B-Cell Lymphoma (ZUMA-7) Session: 905. Outcomes Research-Lymphoid Malignancies: Transplant and Cellular Therapy Abstract No.: 430 Mahmoud Elsawy et al.Based on the results presented, GlobalData inferred that QoL analysis set treated with axi-cel versus SOC, there was a statistically significant (P<.0001) and clinically meaningful difference in mean change of scores from baseline at Day 100 in favor of axi-cel on all prespecified PRO domains (Figure). Sensitivity analyses showed similar results with retained significance at Day 100. Furthermore, scores also significantly favored axi-cel over SOC for EORTC QLQ-C30 Global Health Status/QoL (P=.0124) and EQ-5D-5L VAS (P=.0004) at Day 150. For the prespecified endpoints, the mean estimated scores for the axi-cel arm had numerically returned to or exceeded scores at baseline by Day 150 versus on or after Month 9 for the SOC arm. After Month 9, attrition (eg, due to disease progression, new lymphoma therapy, or death) in the QoL analysis set was substantial, particularly in the SOC arm.https://ash.confex.com/ash/2021/webprogram/Paper147598.html **December 11, 2021** Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma Frederick L. Locke et al The New England Journal of Medicine, 2021 Based on the results reported, Globaldata inferred that a total of 180 patients were randomly assigned to receive axi-cel and 179 to receive standard care. The

primary end-point analysis of event-free survival showed that axi-cel therapy was superior to standard care. At a median follow-up of 24.9 months, the median event-free survival was 8.3 months in the axi-cel group and 2.0 months in the standard-care group, and the 24-month event-free survival was 41% and 16%, respectively (hazard ratio for event or death, 0.40; 95% confidence interval, 0.31 to 0.51; P<0.001). A response occurred in 83% of the patients in the axi-cel group and in 50% of those in the standard-care group (with a complete response in 65% and 32%, respectively). In an interim analysis, the estimated overall survival at 2 years was 61% in the axi-cel group and 52% in the standard-care group. https://www.nejm.org/doi/full/10.1056/NEJMoa2116133

August 04, 2021

Early trial results indicate Yescarta CAR-T therapy improves survival for adults who relapse from large B-cell lymphomaBased on the results announced by University of Kansas Medical Center, in the press release, GlobalData inferred that compared to the standard regimen of chemotherapy and a stem cell transplant), Yescarta improved event-free survival by 60%. https://www.kumc.edu/news-listing-page/zuma-7.html

September 10, 2018

European Medicines Agency (EMA), Committee for Medicinal Products for Human Use (CHMP)
Yescarta (Axicabtagene ciloleucel)– Product Information Based on the results reported, GlobalData inferred that efficacy results were analyzed. **Summary of Efficacy Results for ZUMA-7:**

	Yescarta N = 180	**Care Therapy N = 179**
Event-Free Survival		
Number of events (%)	108 (60)	144 (80)
Median, months [95% CI]	8.3 [4.5, 15.8]	2.0 [1.6, 2.8]
Stratified hazard ratio [95% CI]	0.398 [0.308, 0.514]	
Stratified log-rank p-value	<0.0001	
Objective Response	83 [77.1, 88.5]	50 [42.7, 57.8]

	<table><tr><td>Rate (%) [95% CI]</td><td></td><td></td></tr><tr><td>Odds ratio [95% CI]</td><td colspan="2">5.31 [3.08, 8.90]</td></tr><tr><td>Stratified CMH test p-value</td><td colspan="2"><0.0001</td></tr><tr><td>Complete Response Rate (%)</td><td>65 [57.6, 71.9]</td><td>32 [25.6, 39.8]</td></tr><tr><td>Partial Response Rate (%)</td><td>18 [13.0, 24.8]</td><td>18 [12.6, 24.3]</td></tr></table> https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf **June 28, 2021** Kite Announces Yescarta CAR T-cell Therapy Improved Event-Free Survival by 60% Over Chemotherapy Plus Stem Cell Transplant in Second-Line Relapsed or Refractory Large B-cell Lymphoma Based on the interim results announced by Kite Pharma Inc, in the press release, GlobalData inferred that a median follow-up of two years, the study met the primary endpoint of event-free survival (EFS; hazard ratio 0.398, p <0.0001). The study also met the key secondary endpoint of objective response rate (ORR). The interim analysis of overall survival (OS) showed a trend favoring Yescarta; however, the data are immature at this time, and further analyses are planned for the future. https://www.gilead.com/news-and-press/press-room/press-releases/2021/6/kite-announces-yescarta-car-tcell-therapy-improved-eventfree-survival-by-60-over-chemotherapy-plus-stem-cell-transplant-in-secondline-relapsed-or Based on the results reported, axicabtagene ciloleucel as second-line therapy demonstrated a significant improvement in overall survival, significant event free survival over chemotherapy-based standard of care and progression free survival confirmed benefit in the Yescarta vs. SOC arm in subjects with early relapsed/refractory large B-cell lymphoma.
Safety Result	**March 07, 2024** Study of Effectiveness of Axicabtagene Ciloleucel Compared to Standard of Care Therapy in Patients With Relapsed/Refractory Diffuse Large B Cell Lymphoma (ZUMA-7)Based on the results published, GlobalData inferred that 359 subjects were analyzed in the study

	Axicabtagene Ciloleucel	Standard of Care Therapy
	Affected / at Risk (%)	**Affected / at Risk (%)**
Serious Adverse Events		
Coagulopathy	1/170 (0.59%)	0/168 (0.00%)
Febrile neutropenia	6/170 (3.53%)	22/168 (13.10%)
Non Serious Adverse Events		
Leukopenia	9/170 (5.29%)	6/168 (3.57%)
Neutropenia	75/170 (44.12%)	28/168 (16.67%)

https://classic.clinicaltrials.gov/ct2/show/results/NCT03391466

December 09, 2023

Presented at the 65th American Society of Hematology (ASH 2023) Annual Meeting and Exposition, December 09 - 12, 2023, San Diego, California, USA
Improved Overall Survival with Axicabtagene Ciloleucel Vs Standard of Care in Second-line Large B-cell Lymphoma among the Elderly: A Subgroup Analysis of ZUMA-7
Session: 627. Aggressive Lymphomas: Clinical and Epidemiological: Poster I
Abstract No.: 1761 Marie Jose Kersten et al.Based on the subgroup analysis results presented, GlobalData inferred that there was no new treatment-related deaths reported since the primary EFS analysis. There were no manufacturing failures for any subject who underwent leukapheresis.
https://ash.confex.com/ash/2023/webprogram/Paper173873.html

September 06, 2023

Presented at the 11th Hybrid Annual Meeting of the Society of Hematologic Oncology (SOHO 2023), September 06 - 09, 2023, Houston, Texas, USA Cost-effectiveness of the Chimeric Antigen Receptor (Car) T-cell Treatments, Lisocabtagene Maraleucel (Liso-cel) Versus Axicabtagene Ciloleucel (Axi-cel), as Second-line (2l) Treatment of Large B-cell Lymphoma (Lbcl)
Session: Cellular Therapy
Abstract No.: CT-107 Matthew Lunning et al. Based on the pooled results of GDC40002568 and GDC30008058 presented, GlobalData inferred that the safety profile of lisocabtagene maraleucel, including lower rates of cytokine release syndrome and neurological events, resulted in cost savings and quality-adjusted life-years gains versus axicabtagene ciloleucel. https://clml-soho2023.elsevierdigitaledition.com/index.html NCT03331198

	June 13, 2023 Presented at the 17th International Conference on Malignant Lymphoma (ICML 2023), June 13 - 17, 2023, Lugano, Switzerland Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard of Care in Relapsed/Refractory Large B-cell Lymphoma Session: Session 3 - Treatment of Aggressive Lymphomas Abstract No: 22 Westin J R et al.Based on the results presented, GlobalData inferred that there were no new cytokine release syndrome or neurologic events and no new treatment-related deaths occurred since the primary event free survival(EFS) analysis. The safety profile of axi-cel remained consistent with prior studies.https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22 **June 05, 2023** Kite's Yescarta CAR T-cell Therapy Demonstrates Significantly Longer Overall Survival Versus Standard of Care as Initial Treatment of Relapsed/Refractory Large B-cell LymphomaBased on the results announced by Kite Pharma, in the press release, GlobalData inferred that the primary EFS analysis showed that Grade 3 or higher adverse events (AEs) occurred in 91% of subjects treated with axi-cel compared with 83% of those treated with SOC. The most common grade 3 or higher AEs were neutropenia (69% vs 41%, respectively), anemia (30% vs 39%), and leukopenia (29% vs 22%).https://www.gilead.com/news-and-press/press-room/press-releases/2023/6/kites-yescarta-car-t-cell-therapy-demonstrates-significantly-longer-overall-survival-versus-standard-of-care-as-initial-treatment-of-relapsedrefrac **June 05, 2023** Survival with Axicabtagene Ciloleucel in Large B-Cell Lymphoma Jason R. Westin et al The New England Journal of Medicine, 2023 Based on results reported, Globaldata inferred that no new treatment-related deaths had occurred since the primary analysis of event-free survival.https://www.nejm.org/doi/full/10.1056/NEJMoa2301665 **June 02, 2023** Presented at the 59th Annual Meeting of American Society of Clinical Oncology (ASCO 2023), June 02 - 06, 2023, Chicago, Illinois, USA Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard-of-care Therapy in Relapsed/refractory Large B-cell Lymphoma Session: Clinical Science Symposium- Moving Cellular Therapy Into Earlier Lines of Treatment in Hematologic Malignancies: Latest Efficacy Data and The

	Need to Improve Access Abstract No.: LBA107 Jason Westin et al.Based on the results presented, GlobalData inferred that there were no new cytokine release syndrome or neurologic events and no new treatment-related deaths occurred since the primary EFS analysis.https://meetings.asco.org/abstracts-presentations/220014 **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 Association of Metabolic Tumor Volume (Mtv) and Clinical Outcomes in Second-line Relapsed/Refractory Large B-cell Lymphoma Following Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care (Soc) Therapy in Zuma-7 Session: CAR-based Cellular Therapy – Clinical Abstract No.: P164 Olalekan O Oluwole et al.Based on the results presented, GlobalData inferred that the median MTV was higher for axi-cel subjects who experienced grade ≥3 neurologic events (NEs, n=36) versus subjects who experienced grade 1-2 or no NEs (n=134, 320.9 mL (range, 24.3-13,527.0) versus 193.9 (range, 2.3-16,669.3)). Median MTV was higher for axi-cel subjects who experienced grade ≥3 cytokine release syndrome (CRS, n=11) compared with subjects who experienced grade 1-2 or no CRS (n=159, 582.9 mL (range, 114.6-2508.6) versus 203.3 (range, 2.3-16,669.3)).https://ebmt2023.abstractserver.com/program/#/details/presentations/791 **March 21, 2023** KITE'S YESCARTA CAR T-CELL THERAPY DEMONSTRATES A STATISTICALLY SIGNIFICANT IMPROVEMENT IN OVERALL SURVIVAL FOR INITIAL TREATMENT OF RELAPSED/REFRACTORY LARGE B-CELL LYMPHOMABased on the results announced in the press release, GlobalData inferred that among the 168 Yescarta-treated subjects evaluable for safety, Grade ≥3 cytokine release syndrome (CRS) and neurologic events were observed in 7% and 25% of subjects respectively, in the SOC arm, 83% of subjects had high grade events, mostly cytopenias (low blood counts).https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract **February 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 Outcomes of Subsequent Anti-lymphoma Therapies in Patients with

	Relapsed/Refractory Large B-cell Lymphoma (LBCL) Treated with Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC; ZUMA-7) Session: CAR-based Cellular Therapy – Clinical Abstract No.: P167 Olalekan O Oluwole et al.Based on the results presented, GlobalData inferred that one subject who received 3L axi-cel but no SCT had disease progression and died 8.7 months after retreatment.https://ebmt2023.abstractserver.com/program/#/details/presentations/790 **February 15, 2023** Presented at the 2023 Transplantation & Cellular Therapy (TCT 2023) Meetings, February 15 - 19, 2023, Orlando, Florida, USA Association of Metabolic Tumor Volume (MTV) and Clinical Outcomes in Second-Line (2L) Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Following Axicabtagene Ciloleucel (Axi-Cel) Versus Standard-of-Care (SOC) Therapy in Zuma-7 Session: Poster Session: Immune Reconstitution and Immunobiology Abstract No.: 497 Frederick L Locke et al.Based on the results presented, GlobalData inferred that median MTV was higher for axi-cel subjects who experienced Grade ≥3 neurologic events (NEs; n=36) vs subjects who experienced Grade 1-2 or no NEs (n=134; 320.9 mL [range, 24.3-13,527.0] vs 193.9 [range, 2.3-16,669.3]). Median MTV was higher for axi-cel subjrcts who experienced Grade ≥3 cytokine release syndrome (CRS; n=11) vs subjects who experienced Grade 1-2 or no CRS (n=159; 582.9 mL [range, 114.6-2508.6] vs 203.3 [range, 2.3-16,669.3]).https://astct-29-s2.elsevierdigitaledition.com/ **December 11, 2022** Body of Evidence Grows From ZUMA-7 Study Supporting Initial Treatment With Kite's Yescarta CAR T-Cell Therapy for Patients With Relapsed or Refractory Large B-Cell LymphomaBased on the results announced by Kite, in the press release, GlobalData inferred that in the yescarta arm, median metabolic tumor volume (MTV) was higher in subjects who experienced grade ≥3 neurologic events or grade ≥3 cytokine release syndrome (CRS) compared with subjects who experienced grade 1-2 or no neurologic events or grade 1-2 or no cytokine release syndrome (CRS), respectively.https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/body-of-evidence-grows-from-zuma-7-study-supporting-initial-treatment-with-kites-yescarta-car-t-cell-therapy-for-patients-with-relapsed-or-refractor **December 10, 2022** Presented at the 64th Hybrid American Society of Hematology (ASH 2022) Annual Meeting and Exposition, December 10 - 13, 2022, New Orleans,

	Louisiana, USA Association of Metabolic Tumor Volume (MTV) and Clinical Outcomes in Second-Line (2L) Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Following Axicabtagene Ciloleucel (Axi-Cel) Versus Standard-of-Care (SOC) Therapy in ZUMA-7 Session: 705. Cellular Immunotherapies: Novel Predictors of Response or Toxicity to Cellular Therapies Abstract No.: 259 Frederick L. Locke et al.Based on the results presented, GlobalData inferred that in axi-cel subjects, median metabolic tumor volume (MTV) was higher for subjects who experienced grade ≥3 neurologic events (n=36) versus subjects who experienced grade 1-2 or no neurologic events (n=134; 320.9 mL (range, 24.3-13,527.0) versus 193.9 (range, 2.3-16,669.3)). Median MTV was higher for axi-cel subjects who experienced grade ≥3 cytokine release syndrome (CRS; n=11) compared with subjects who experienced grade 1-2 or no CRS (n=159, 582.9 mL (range, 114.6-2508.6) versus 203.3 (range, 2.3-16,669.3)). Rates of grade ≥3 neurologic events and CRS were associated with higher MTV.https://ash.confex.com/ash/2022/webprogram/Paper158492.html **December 10, 2022** Presented at the 64th Hybrid American Society of Hematology (ASH 2022) Annual Meeting and Exposition, December 10 - 13, 2022, New Orleans, Louisiana, USA Matching-adjusted Indirect Comparison (MAIC) of Lisocabtagene Maraleucel (Liso-cel) Versus Axicabtagene Ciloleucel (Axi-cel) for Second-line (2L) Treatment of Patients (Pt) with Refractory/Early Relapsed (R/R) Large B-cell Lymphoma (LBCL) Session: 705. Cellular Immunotherapies: Late Phase and Commercially Available Therapies: Poster I Abstract No.: 4673 Jeremy S Abramson et al.Based on the pooled results of and GDC30008058 and GDC40002568 presented, GlobalData inferred that MAIC safety results showed lower odds of key CAR T cell–associated adverse events (AEs) with liso-cel vs axi-cel: cytokine release syndrome (CRS) any grade, CRS grade ≥ 3, neurological events (NE) any grade, and NEs grade ≥ 3. Lisocabtagene maraleucel had a better safety profile than axicabtagene ciloleucel in second line treatment of refractory/relapsed large B-cell lymphoma and were consistent with those from the third-line+ MAIC analysis. https://ash.confex.com/ash/2022/webprogram/Paper160216.htmlhttps://ashpublications.org/blood/article/140/Supplement%201/4655/490968/Matching-Adjusted-Indirect-Comparison-MAIC-of?searchresult=1 **June 11, 2022** Presented at the 27th *Hybrid* Annual Congress of the European Hematology Association (EHA 2022), June 09 - 12, 2022, Vienna, Austria Clinical and Patient-Reported Outcomes in a Phase 3 Study of Axicabtagene Ciloleucel (Axi-Cel) vs Standard-of-Care in Elderly Patients With

	Relapsed/Refractory Large B-Cell Lymphoma (Zuma-7) Session: Oral Presentation: Aggressive Lymphoma - CART Abstract No.: S211 Anna Sureda et al.Based on the results presented, GlobalData inferred that grade ≥3 treatment-emergent adverse events occurred in 94% and 82% of axicabtagene ciloleucel and standard-of-care subjects, respectively. Grade 5 treatment-related adverse events occurred in 0 and 1 subject of axicabtagene ciloleucel and standard-of-care subjects, respectively.https://library.ehaweb.org/eha/2022/eha2022-congress/357075/anna.sureda.clinical.and.patient-reported.outcomes.in.a.phase.3.study.of.html?f=menu%3D6%2Abrowseby%3D8%2Asortby%3D2%2Amedia%3D3%2Ace_id%3D2233%2Aot_id%3D26858%2Amarker%3D1751 **June 04, 2022** Presented at the 58th Annual Meeting of American Society of Clinical Oncology (ASCO 2022), June 03 - 07, 2022, Chicago, Illinois, USA Clinical and Patient (Pt)-reported Outcomes (PROs) in a Phase 3, Randomized, Open-label Study Evaluating Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care (SOC) Therapy in Elderly Pts with Relapsed/Refractory (R/R) Large B-cell Lymphoma (LBCL; Zuma-7) Session: Poster Session- Hematologic Malignancies—Lymphoma and Chronic Lymphocytic Leukemia Abstract No.: 7548 Jason Westin et al.Based on the results presented, GlobalData inferred that Axi-cel demonstrated a manageable safety profile. Grade ≥3 Tx-emergent adverse events (AEs) occurred in 94% and 82% of axi-cel and SOC subjects, respectively, and Grade 5 Tx-related AEs occurred in 0 and 1 subject. https://meetings.asco.org/abstracts-presentations/209923 **June 04, 2022** Sub-analyses of Landmark ZUMA-7 Trial Reinforce Yescarta CAR T-cell Therapy Superiority Over Standard of Care (SOC) as Initial Treatment for Patients With Relapsed or Refractory Large B-cell Lymphoma (LBCL)Based on the results reported in the press release, GlobalData inferred that the safety profile of Yescarta was consistent with previous studies and real-world data in subjects of all ages. Rates of cytokine release syndrome (CRS) and neurologic events (NE) for subjects 65 and older were slightly higher than those observed in the overall patient population. Notably, compared with SOC subjects, more Yescarta subjects had high-risk features at baseline, including second-line age-adjusted International Prognostic Index (IPI) 2-3 (53% vs 31%), elevated LDH (61% vs 41%), and high grade B-cell lymphoma (including double/triple-hit-lymphoma (33% vs 14%)).

	https://www.businesswire.com/news/home/20220604005006/en/Sub-analyses-of-Landmark-ZUMA-7-Trial-Reinforce-Yescarta%C2%AE-CAR-T-cell-Therapy-Superiority-Over-Standard-of-Care-SOC-as-Initial-Treatment-for-Patients-With-Relapsed-or-Refractory-Large-B-cell-Lymphoma-LBCL **May 16, 2022** Presented at the 25th Hybrid Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT 2022), May 16 - 19, 2022, Washington, D.C, USA Primary Analysis of ZUMA7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-Cel) versus StandardofCare (SOC) Therapy in Patients (Pts) with Relapsed/ Refractory (R/R) Large B-Cell Lymphoma (LBCL) Session: Cancer - Targeted Gene and Cell Therapy II Abstract No.: 1113 Armin Ghobadi et al.Based on the results presented, GlobalData inferred that the grade ≥3 adverse events occurred in 155 (91%) and 140 (83%) subjects, and treatment-related deaths occurred in 1 and 2 axicabtagene ciloleucel and standard of care subjects, respectively. Grade ≥3 cytokine release syndrome (CRS) occurred in 11 (6%) axicabtagene ciloleucel subjects and grade ≥3 neurologic events (NEs) in 36 (21%). No grade 5 cytokine release syndrome or neurologic events occurred. In ZUMA-7, axicabtagene ciloleucel demonstrated a statistically significant improvement over standard of care with >4-fold greater median EFS, double the CR rate, and nearly 3× more subjects receiving definitive therapy.https://www.cell.com/molecular-therapy-family/molecular-therapy/pdf/S1525-0016(22)00246-5.pdf **April 27, 2022** FDA Approves Axicabtagene Ciloleucel for Second-Line Treatment of Large B-Cell LymphomaBased on the results reported in the press release, GlobalData inferred that axicabtagene ciloleucel in subjects with non-Hodgkin lymphoma, CRS occurred in 90% (Grade ≥3, 9%) and neurologic toxicities occurred in 78% (Grade ≥3, 25%). The most common non-laboratory adverse reactions (incidence ≥30%) are CRS, fever, hypotension, encephalopathy, fatigue, tachycardia, headache, nausea, febrile neutropenia, diarrhoea, musculoskeletal pain, infections with pathogen unspecified, chills, and decreased appetite.https://www.esmo.org/oncology-news/fda-approves-axicabtagene-ciloleucel-for-second-line-treatment-of-large-b-cell-lymphoma **April 26, 2022** Presented at The 2022 Transplantation & Cellular Therapy (TCT 2022) Meetings, April 23 - 26, 2022, Salt Lake City, Utah, USA Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-Cel) Versus Standard of Care (SOC) Therapy in Patients with Relapsed/Refractory Large B-Cell

	Lymphoma Session: Tandem Meetings Best Abstracts Abstract No.: 1 Frederick L. Locke et al.Based on the results presented, GlobalData inferred that grade ≥3 treatment-emergent adverse events occurred in 155(91%) and 140(83%) subjects, and treatment-related deaths occurred in 1 and 2 subjects in the axi-cel and SOC cohorts, respectively. In axi-cel subjects, grade ≥3 cytokine release syndrome(CRS) occurred in 11(6%) subjects and grade ≥3 neurologic events(NEs) occurred in 36 (21%) subjects. No grade 5 cytokine release syndrome or neurologic events occurred. Safety of axi-cel was manageable and consistent with third-line axi-cel therapy.https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19266 **March 23, 2022** Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel(axi-Cel) Versus Standard of Care(soc) Therapy in Patients With Relapsed/Refractory Large B-Cell Lymphoma Session: OS13 Oral session 13: CAR-T II Abstract No.: OS13-06 Tom van Meerten et al.Based on the results presented, GlobalData inferred that grade ≥3 treatment-emergent adverse events occurred in 155 (91%) and 140 (83%) subjects, and treatment-related deaths occurred in 1 and 2 subjects in the axi-cel and SOC arms, respectively.https://ebmt2022.abstractserver.com/program/#/details/presentations/855 **March 22, 2022** Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Superiority of Axicabtagene Ciloleucel (Axi-cel) in Second-line (2l) Large B-cell Lymphoma (Lbcl) in the Elderly Session: OS08 Oral session 8: CAR-T I Abstract No.: OS08-05 Tom van Meerten et al.Based on the results presented, GlobalData inferred that grade ≥3 treatment-emergent adverse events occurred in 46/49 (94%) of axi-cel subjects and 45/55 (82%) of standard-of-care subjects. Treatment-related grade 5 Adverse events occurred in 0 and 1subjects, respectively, in the axi-cel and standard of care arms. Axi-cel subjects experienced grade 3 cytokine release syndrome and neurologic events in 4 (8%) and 13 (27%) cases, respectively. There were no grade 5 cytokine release syndrome or neurologic events..https://ebmt2022.abstractserver.com/program/#/details/presentations/819

	December 12, 2021 Presented at the 63rd Virtual American Society of Hematology (ASH 2021) Annual Meeting and Exposition, December 11 - 14, 2021, Atlanta, Georgia, USA Primary Analysis of Zuma-7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care Therapy in Patients with Relapsed/Refractory Large B-cell Lymphoma Session: Plenary Scientific Sessiona Abstract No.: 2 Frederick L Locke et al.Based on the results presented, GlobalData inferred that grade ≥3 treatment-emergent adverse events occurred in 155 (91%) and 140 (83%) subjects, and Tx-related deaths occurred in one and two subjects in the axi-cel and standard of care arms, respectively. In subjects treated with axi-cel, grade ≥3 cytokine release syndrome (CRS) occurred in 11 (6%) subjects (median time to onset 3 d; median duration 7 d) and grade ≥3 neurologic events (NEs) occurred in 36 (21%) subjects (median time to onset 7 d; median duration 8.5 d). Grade 5 cytokine release syndrome or neurologic events not observed in the study. Safety of axi-cel was manageable and at least consistent with 3L axi-cel therapy. https://ash.confex.com/ash/2021/webprogram/Paper148039.html **December 11, 2021** Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma Frederick L. Locke et al The New England Journal of Medicine, 2021 Based on the results reported, Globaldata inferred that adverse events of grade 3 or higher occurred in 91% of the patients who received axi-cel and in 83% of those who received standard care. Among patients who received axi-cel, grade 3 or higher cytokine release syndrome occurred in 6% and grade 3 or higher neurologic events in 21%. No deaths related to cytokine release syndrome or neurologic events occurred.https://www.nejm.org/doi/full/10.1056/NEJMoa2116133 **August 04, 2021** Early trial results indicate Yescarta CAR-T therapy improves survival for adults who relapse from large B-cell lymphomaBased on the results announced by University of Kansas Medical Center, in the press release, GlobalData inferred that the safety results were as good or better than they were for existing third-line Yescarta treatment. https://www.kumc.edu/news-listing-page/zuma-7.html **September 10, 2018**

	European Medicines Agency (EMA), Committee for Medicinal Products for Human Use (CHMP) Yescarta (Axicabtagene ciloleucel)– Product Information Based on the results reported, GlobalData inferred that safety results were analyzed. The most significant and frequently occurring adverse reactions were CRS (92%), encephalopathy (49%), and infections (45%). Serious adverse reactions occurred in 54% of patients. The most common (≥ 5%) serious adverse reactions included CRS (17%), encephalopathy (16%), unspecified pathogen infections (8%), fever (6%) and viral infection (5%) The most common (≥ 5%) Grade 3 or higher non-haematological adverse reactions included encephalopathy (19%), unspecified pathogen infections (8%), CRS (6%), and bacterial infection (5%). The most common Grade 3 or higher haematological adverse reactions included lymphopenia (99%), leukopenia (95%), neutropenia (94%), anaemia (41%), and thrombocytopenia (26%). Encephalopathy and tremor were reported in 49% and 25% of patients treated with Yescarta compared to 8% and 1% treated with SOCT. Febrile neutropenia and viral infection were reported in 2% and 16% of patients treated with Yescarta compared to 27% and 5% treated with SOCT. Grade 3 or higher neutropenia and thrombocytopenia were reported in 94% and 26% of patients treated with Yescarta compared to 51% and 63% treated with SOCT, respectively. https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf **June 28, 2021** Kite Announces Yescarta CAR T-cell Therapy Improved Event-Free Survival by 60% Over Chemotherapy Plus Stem Cell Transplant in Second-Line Relapsed or Refractory Large B-cell Lymphoma Based on the interim results announced by Kite Pharma Inc, in the press release, GlobalData inferred that the safety results from the study were consistent with or lower than the known safety profile of Yescarta for the treatment of LBCL in the third-line setting. Six percent of patients experienced cytokine release syndrome (CRS) Grade 3 or higher, with a median onset of three days, and 21% experienced neurological events Grade 3 or higher. No new safety concerns were identified in this second-line setting. https://www.gilead.com/news-and-press/press-room/press-releases/2021/6/kite-announces-yescarta-car-tcell-therapy-improved-eventfree-survival-by-60-over-chemotherapy-plus-stem-cell-transplant-in-secondline-relapsed-or
Pharmacokinetic Evaluation	

	April 10, 2022 Presented at the 113th Annual Meeting of the American Association for Cancer Research (AACR 2022), April 08 - 13, 2022, New Orleans, Louisiana, USA Product attributes of axicabtagene ciloleucel (axi-cel) that associate differentially with efficacy and toxicity in second-line large B-cell lymphoma Session: CTPL01 - Clinical Trials of Cellular Immunotherapies Abstract No.: CT004 Jason R Westin et al. Based on the results presented, GlobalData inferred that the median (Q1, Q3 n is 162) peak chimeric antigen receptor T--cell level, time to peak, and area under the curve within the first 28 days of treatment (AUC_{0-28}) were 25.8 cells/µL (8.2, 57.9), 8 days (8, 9), and 236.2 cells/µLdays (76.4, 758.0), respectively.https://www.abstractsonline.com/pp8/#!/10517/presentation/20146

Statistical Method (if any)	**December 09, 2023** Presented at the 65th American Society of Hematology (ASH 2023) Annual Meeting and Exposition, December 09 - 12, 2023, San Diego, California, USA Statistical Challenges from Trials of Potentially Curative Treatments: Validation of Cure Assumptions When Analyzing Zuma-7 Follow-up Data of Axi-cel and Standard of Care Therapy Session: 705.Cellular Immunotherapies: Late Phase and Commercially Available Therapies Abstract No.: 6899 Anik R Patel et al.Based on the results presented, GlobalData inferred that kaplan-meier estimates and mixture cure modeling (MCM) were used in the study.https://ashpublications.org/blood/article/142/Supplement%201/6899/500947/Statistical-Challenges-from-Trials-of-Potentially **December 09, 2023** Presented at the 65th American Society of Hematology (ASH 2023) Annual Meeting and Exposition, December 09 - 12, 2023, San Diego, California, USA Improved Overall Survival with Axicabtagene Ciloleucel Vs Standard of Care in Second-line Large B-cell Lymphoma among the Elderly: A Subgroup Analysis of ZUMA-7 Session: 627. Aggressive Lymphomas: Clinical and Epidemiological: Poster I Abstract No.: 1761 Marie Jose Kersten et al.Based on the subgroup analysis results presented, GlobalData inferred that multivariate analyses and piecewise Cox regression model were used in the study.https://ash.confex.com/ash/2023/webprogram/Paper173873.html **June 13, 2023** Presented at the 17th International Conference on Malignant Lymphoma (ICML 2023), June 13 - 17, 2023, Lugano, Switzerland Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard of Care in Relapsed/Refractory Large B-cell Lymphoma Session: Session 3 - Treatment of Aggressive Lymphomas Abstract No: 22 Westin J R et al.Based on the results presented, GlobalData

	inferred that log rank analysis was used in this study.https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
	April 11, 2022
	Presented at the 113th Annual Meeting of the American Association for Cancer Research (AACR 2022), April 08 - 13, 2022, New Orleans, Louisiana, USA
	Gender bias in the association of pre-treatment cytokine signatures with response and survival in B cell lymphoma patients treated with anti-CD19 CAR T-cell therapy Session: PO.CL11.07 - Biomarkers Predictive of Therapeutic Benefit 2 Abstract No.: 1262 / 9
	Manishkumar S. Patel et al.Based on the results reported, GlobalData inferred that multiplexed bead arrays, unpaired Wilcoxon test, Kaplan-Meier survival analysis were used in the analysis. Statistical analyses were performed using R and $p<0.05$ was considered significant.https://www.abstractsonline.com/pp8/#!/10517/presentation/12678
	March 23, 2022

	Presented at the 48th Virtual Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT 2022), March 19 - 23, 2022, Prague, Czech Republic Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel(axi-Cel) Versus Standard of Care(soc) Therapy in Patients With Relapsed/Refractory Large B-Cell Lymphoma Session: OS13 Oral session 13: CAR-T II Abstract No.: OS13-06 Tom van Meerten et al.Based on the results presented, GlobalData inferred that Kaplan-Meier method was used in this study.https://ebmt2022.abstractserver.com/program/#/details/presentations/855
Conclusion	The trial was completed. Based on the results reported, GlobalData concluded that yescarta is safe and shows significant improvement in response rate, progression free survival benefit, significant event free survival compared to standard of care in second-line relapsed or refractory large B-cell lymphoma subjects.

Trial Cost Overview	
Trial Cost Parameters	**Cost ($ Millions)**
Trial Cost	47.18
Trial Cost/Month	1.23
Trial Cost/Site	0.61
Trial Cost/Subject	0.13

Trial Cost By Year	
Year	**Trial Cost ($ Millions)**
2018	13.88
2019	14.65
2020	14.65
2021	3.09

Trial Cost By Components	
Cost Components	**Cost ($ Millions)**
Admin Costs	4.72
Central Lab	5.66
Subject Costs	5.19
Personnel Costs	12.27
Site Costs	19.34

Investigators Information			
Name	Catherine Thieblemont	Role	Principal Investigator
Specialty	Hematology; Oncology	Board Certification	
Primary Designation	Professor	Associated Organization	University Paris 7 - Denis Diderot
Contact Number	33-1-42499236; 33-1-42499236; 33-1-42494949; 33-1-42499140; 33-1-44274427	Email	catherine.thieblemont@sls.aphp.fr; catherine.thieblemont@aphp.fr
State	Ile de France	Country	France

Similar studies done by Investigator

Investigators Information			
Name	Brian T Hill	Role	Principal Investigator
Specialty	Hematology; Internal Medicine; Medical Oncology; Oncology; Clinical genetics	Board Certification	
Primary Designation	Associate Professor	Associated Organization	Cleveland Clinic Lerner College of Medicine
Contact Number	1-216-4459451; 1-886-2238100; 1-216-3682000	Email	hillb2@ccf.org
State	Ohio	Country	United States

Similar studies done by Investigator

Investigators Information			
Name	David B Miklos	Role	Principal Investigator
Specialty	Hematology; Internal Medicine; Medical Oncology	Board Certification	
Primary Designation	Professor	Associated Organization	Stanford University
Contact Number	1-650-4986000; 1-650-7230822; 1-650-7254626	Email	dmiklos@stanford.edu
State	California	Country	United States

Similar studies done by Investigator

Investigators Information			
Name	David G Maloney	Role	Co-Author
Specialty	Hematology; Internal Medicine; Medical Oncology; Oncology	Board Certification	
Primary Designation	Professor	Associated Organization	University of Washington School of Medicine
Contact Number	1-206-6675836; 1-206-6675616; 1-206-5984100; 1-206-5436420	Email	dmaloney@fredhutch.org; dmaloney@fhcrc.org
State	Washington	Country	United States

Similar studies done by Investigator

Investigators Information			
Name	Christian Gisselbrecht	Role	Co-Author
Specialty	Hematology; Oncology	Board Certification	
Primary Designation	Emeritus Professor	Associated Organization	Paris Diderot University
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			christian.gisselbrecht@sls.ap-hop-paris.fr
State	Ile de France	Country	France

Similar studies done by Investigator

Location(s) (78)					
Region	**Country**	**State**	**Trial Site**	**Address**	**Status**
Asia-Pacific	Australia	Victoria	Peter MacCallum Cancer Centre	Peter MacCallum Cancer Center, Melbourne, Victoria, Australia, 3000	Completed
Europe	Austria	Styria	LKH University Hospital Graz	Universitatsklinikum Graz, Division of Hematology, Graz, Styria, Austria, 6020	Completed
Europe	Austria	Tyrol	Innsbruck Medical University	Medizinische Universitat Innsbruck, Innere Medizin V - Hamatologie und Onkologie, Innsbruck, Tyrol, Austria, 6020	Completed
Europe	Belgium	Brussels	Saint Luc University Hospital	Cliniques Universiaires Saint-Luc, Brussels, Brussels, Belgium	Completed
Europe	Belgium	Flemish Brabant	University Hospitals Leuven	UZ Gasthuisberg, Leuven,	Completed

				Flemish Brabant, Belgium	
Europe	France		Hopital Claude Huriez	CHRU de Lille - Hopital Claude Huriez, Lille cedex, France, 59037	Completed
Europe	France	Brittany	Hospital Pontchaillou	Centre Hospitalier Universitaire de Rennes - Hopital Pontchaillou, Rennes, Brittany, France, 35033	Completed
Europe	France	Ile de France	Saint-Louis Hospital	Hopital Saint-Louis, Paris, Ile de France, France, 75010	Completed
Europe	France	Pays de la Loire	Nantes University Hospital	Centre Hospitalier Universataire de Nantes, Nantes, Pays de la Loire, France, 44000	Completed
Europe	France	Pierre Benite	Centre Hospitalier Lyon Sud	Centre Hospitalier Lyon-Sud - Service d'Hematologie clinique, Pierre Benite, France, 69495	Completed
Europe	Germany	Baden-Wuerttemberg	Heidelberg University Hospital	Universitatsklinikum Heidelberg, Heidelberg, Baden-Wuerttemberg, Germany,	Completed

				69120	
Europe	Germany	Bavaria	Wurzburg University Hospital	Universitats-klinikum Wurzburg, Wurzburg, Bavaria, Germany, 97080	Completed
Europe	Germany	Hamburg	University Medical Center Hamburg-Eppendorf	Universitatsklinikum Hamburg-Eppendorf, Hamburg, Hamburg, Germany, 20246	Completed
Europe	Germany	North Rhine-Westphalia	University Hospital Munster	Universitatsklinikum Munster, Munster, North Rhine-Westphalia, Germany, 48149	Completed
Europe	Germany	Saxony	University of Dresden	Universitats-klinikum Dresden, Dresden, Saxony, Germany, 01307	Completed
Europe	Germany	Saxony	University Medical Center Gottingen	Universitatsmedizin Gottingen, Gottingen, Germany, 37075	Completed
Europe	Italy		Institute of Hematology Lorenzo and Ariosto Seragnoli	Instituto di Ematologia "L. e A. Seragnoli" - Dipartimento di Medicina Specialistica	Completed

				Diagnostica e Sperimentale, Bologna, Italy, 40138	
Europe	Italy	Milan	IRCCS San Raffaele Hospital	IRCCS Ospedale San Raffaele di Milano, Milano, Italy, 20132	Completed
Europe	Netherlands	Eponymous	University Medical Center Groningen	University Medical Center Groningen, Groningen, Netherlands, 9700 RB	Completed
Europe	Netherlands	North Holland	Academic Medical Center	Academic Medical Center, Amsterdam, North Holland, Netherlands, 1105 AZ	Completed
Europe	Netherlands	South Holland	Erasmus MC	Erasmus Medical Center, Rotterdam, South Holland, Netherlands, 3011PL	Completed
Europe	Netherlands	Utrecht	University Medical Center Utrecht	University Medical Center Utrecht, Utrecht, Utrecht, Netherlands	Completed
Europe	Spain		Clinica Universidad de Navarra	Clinica Universidad de Navarra, Pamplona, Spain, 31008	Completed

Europe	Spain	Barcelona	Hospital Clinic i Provincial de Barcelona	Hospital Clinic de Barcelona, Barcelona, Barcelona, Spain, 08036	Completed
Europe	Spain	Barcelona	Institut Catala d'Oncologia	Institut Catala d'Oncologia, Barcelona, Barcelona, Spain, 08908	Completed
Europe	Spain	Madrid	La Paz University Hospital	Hospital Universitario La Paz, Madrid, Madrid, Spain, 28046	Completed
Europe	Spain	Salamanca	Hospital Universitario de Salamanca	Hospital Universitario de Salamanca, Salamanca, Salamanca, Spain, 37007	Completed
Europe	Sweden	Scania	Skane University Hospital	Skane University Hospital, Lund, Scania, Sweden, SE 221 85	Completed
Europe	Sweden	Uppland	Uppsala University Hospital	Uppsala Akademiska Sjukhus, Uppsala, Uppland, Sweden, 75185	Completed
Europe	Switzerland		University Hospital Zurich	University Hospital Zurich, Zurich, Switzerland, 8091	Completed
Europe	Switzerland	Bern	Istituto Oncologico della Svizzera Italiana	IOSI, OSpedale Regionale	Completed

				Bellinzona e Valli, Bellinzona, Switzerland, 6500	
Europe	Switzerland	Vaud	Lausanne University Hospital	Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne, Switzerland, 1011	Completed
Europe	United Kingdom	England	University College London Hospitals	University College London Hospitals NHS Foundation Trust, London, England, United Kingdom, NW3 2QG	Completed
Europe	United Kingdom	England	The Christie NHS Foundation Trust	The Christie NHS Foundation Trust, Manchester, England, United Kingdom, M20 4BX	Completed
Europe	United Kingdom	England	Barts Health NHS Trust	Barts Health NHS Trust, London, England, United Kingdom, EC1A 7BE	Completed
Europe	United Kingdom	Kent	Queen Elizabeth Hospital Birmingham	University Hospitals Birmingham NHS	Completed

				Foundation Trust, Birmingham, United Kingdom, B15 2GW	
Europe	United Kingdom	Surrey	The Royal Marsden NHS Foundation Trust	The Royal Marsden NHS Foundation Trust, Sutton, Surrey, United Kingdom, SM2 5PT	Completed
Middle East and Africa	Israel	Tel Aviv	Tel Aviv Sourasky Medical Center	Tel Aviv Sourasky Medical Center, Tel Aviv, Tel Aviv, Israel, 6423906	Completed
North America	Canada		University Hospital of Quebec	CHU de Quebec-Universite Laval, Hopital de L'Enfante-Jesus, Quebec, Canada, G1J 1Z4	Completed
North America	Canada		McGill University Health Center	McGill University Health Center, Montreal, Quebec, Canada, H4A 3J1	Completed
North America	Canada	British Columbia	Vancouver General Hospital	Vancouver General Hospital, Vancouver, British Columbia, Canada	Completed
North America	Canada	Manitoba	CancerCare	CancerCare	Completed

			Manitoba	Manitoba, Winnipeg, Manitoba, Canada, R3E 0V9	
North America	Canada	Nova Scotia	Queen Elizabeth II Health Sciences Centre	QEII Health Sciences Centre, Halifax, Nova Scotia, Canada, B3H 2Y9	Completed
North America	Canada	Ontario	The Ottawa Hospital	The Ottawa Hospital - General Campus, Ottawa, Ontario, Canada, K1H 8L6	Completed
North America	Canada	Ontario	The Princess Margaret Cancer Centre	Uninversity Health Network - Princess Margaret Cancer Center, Toronto, Ontario, Canada, M5G 2M9	Completed
North America	Canada	Quebec	Centre integre universitaire de sante et de services sociaux de l’Est-de-lile-de-Montreal	Centre Integre Universitaire de Sante et Services Sociaux de l'Est-de-l'lle-de-Montreal / Hopital Maisonneuve-Rosemont, Montreal, Quebec, Canada, H1T 2M4	Completed

North America	United States	Alabama	UAB Minority Health and Health Equity Research Center	University of Alabama at Birmingham, Birmingham, Alabama, United States, 35233	Completed
North America	United States	Arizona	Banner Health	Banner MD Anderson Cancer Center, Gilbert, Arizona, United States, 85234	Completed
North America	United States	Arizona	Mayo Clinic	Mayo Clinic Hospital, Phoenix, Arizona, United States, 85054	Completed
North America	United States	California	Stanford Cancer Institute	Stanford Cancer Institute, Stanford, California, United States, 94305	Completed
North America	United States	California	UC San Diego Moores Cancer Center	UC San Diego Moores Cancer Center, La Jolla, California, United States, 92093	Completed
North America	United States	California	University of California Los Angeles	UCLA, Santa Monica, California, United States, 90404	Completed
North America	United States	Florida	H. Lee Moffitt Cancer Center & Research Institute Inc	Moffitt Cancer Center, Tampa, Florida, United	Completed

				States, 12902	
North America	United States	Florida	University of Miami	University of Miami Hospital and Clinics/Sylvester Comprehensive Cancer Center, Miami, Florida, United States, 33136	Completed
North America	United States	Illinois	University of Chicago Medical Center	University of Chicago Medical Center, Chicago, Illinois, United States, 60637	Completed
North America	United States	Illinois	Northwestern University	Northwestern University, Chicago, Illinois, United States, 60612	Completed
North America	United States	Iowa	University of Iowa	University of Iowa Hospitals and Clinincs, Iowa City, Iowa, United States, 52242	Completed
North America	United States	Kansas	University of Kansas Cancer Center	The University of Kansas Cancer Center, Kansas City, Kansas, United States, 66160	Completed
North America	United States	Maryland	University of Maryland	University of Maryland, Greenbaum Comprehensive Cancer Center, Baltimore, Maryland,	Completed

				United States, 21201	
North America	United States	Massachusetts	Dana-Farber Cancer Institute Inc	Dana-Farber Cancer Institute, Boston, Massachusetts, United States, 02215	Completed
North America	United States	Michigan	Barbara Ann Karmanos Cancer Institute	Barbara Ann Karmanos Cancer Institute, Detroit, Michigan, United States, 48201	Completed
North America	United States	Minnesota	Mayo Clinic	Mayo Clinic, Patient Location, Rochester, Minnesota, United States, 55905	Completed
North America	United States	Missouri	Washington University in St Louis	Washington University School of Medicine, Saint Louis, Missouri, United States, 63130	Completed
North America	United States	New Jersey	John Theurer Cancer Center	John Theurer Cancer Center at Hackensack University Medical Center, Hackensack, New Jersey, United States, 07601	Completed
North America	United States	New York	Memorial Sloan	Memorial	Completed

			Kettering Cancer Center	Sloan Kettering Cancer Center, New York, New York, United States, 10021	
North America	United States	New York	Icahn School of Medicine at Mount Sinai	Icahn School of Medicine at Mount Sinai, New York, New York, United States, 10029	Completed
North America	United States	New York	University of Rochester Medical Center	University of Rochester Medical Center, Rochester, New York, United States, 14642	Completed
North America	United States	Ohio	Cleveland Clinic	Cleveland Clinic, Cleveland, Ohio, United States, 44195	Completed
North America	United States	Ohio	Ohio State University	James Cancer Hospital and Solove Research Institute at The Ohio State University Comprehensive Cancer Center, Columbus, Ohio, United States, 43210	Completed
North America	United States	Pennsylvania	UPMC Hillman Cancer Center	UPMC Hillman Cancer Center,	Completed

				Pittsburgh, Pennsylvania, United States, 15213	
North America	United States	Pennsylvania	Thomas Jefferson University	Thomas Jefferson University, Philadelphia, Pennsylvania, United States, 19107	Completed
North America	United States	Tennessee	Henry-Joyce Cancer Clinic	Henry-Joyce Cancer Center, Nashville, Tennessee, United States, 37232	Completed
North America	United States	Tennessee	Sarah Cannon Research Institute LLC	Sarah Cannon Research Institute, Nashville, Tennessee, United States, 37203	Completed
North America	United States	Tennessee	Vanderbilt University	Vanderbilt University, Nashville, Tennessee, United States, 37232	Withdrawn
North America	United States	Texas	University of Texas MD Anderson Cancer Center	The University of Texas, MD Anderson Cancer Center, Houston, Texas, United States, 77030	Completed
North America	United States	Utah	Huntsman Cancer Institute	University of Utah, Huntsman Cancer Institute, Salt Lake City,	Completed

				Utah, United States, 84112	
North America	United States	Virginia	UVA Health	University of Virginia Health System, Charlottesville, Virginia, United States, 22908	Completed
North America	United States	Washington	Swedish Cancer Institute	Swedish Cancer Institute, Seattle, Washington, United States, 98104	Completed

Investigator Affiliated Site(s)(216)					
Region	**Country**	**State**	**Trial Site**	**Address**	**Status**
North America	United States	Pennsylvania	Abramson Cancer Center	Philadelphia, Pennsylvania, 19104, United States	
North America	United States	Ohio	Arthur G. James Cancer Hospital & Richard J Solove Research Institute	300 W 10th Ave, Columbus, Ohio 43210	
North America	United States	Missouri	Barnes-Jewish Hospital	One Barnes-Jewish Hospital Plaza, St. Louis, MO, 63110	
North America	United States	Massachusetts	Brigham and Women's Hospital	75 Francis Street, Boston MA 02115	
North America	United States	Ohio	Case Comprehensive Cancer Center	Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH, 44195	

North America	United States	West Virginia	Charleston Area Medical Center Health System Inc	3200 MacCorkle Ave SE, Charleston, WV 25304	
North America	United States	Ohio	Cleveland Clinic Lerner College of Medicine	9500 Euclid Ave./NA21, Cleveland, OH 44195	
North America	United States	Massachusetts	Dana-Farber/Harvard Cancer Center	75 Francis St. Thorn 604/603b, Boston, MA 02115	
North America	United States	California	David Geffen School of Medicine at UCLA	885 Tiverton Drive Suite B27, Los Angeles, CA 90095	
North America	United States	Illinois	Feinberg School of Medicine	Arthur J. Rubloff Building420 East Superior StreetChicago, IL 60611	
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 Jersey	Hackensack University Medical Center	30 Prospect Avenue, Hackensack, NJ 07601	
North America	United States	Massachusetts	Harvard Medical School	25 Shattuck Street, Boston, MA, 02115	
North America	United States	Iowa	Holden	200 Hawkins	

			Comprehensive Cancer Center	Dr Fl 1, Iowa City, IA 52242	
North America	United States	Pennsylvania	Hospital of the University of Pennsylvania	3400 Spruce Street, Philadelphia, PA, 19104	
North America	United States	New Jersey	Jersey Shore University Medical Center	1945 Route 33 Neptune, NJ 07753	
North America	United States	Maryland	Johns Hopkins University	901 S. Bond Street / Suite 540, Baltimore, MD 21231	
North America	United States	Wisconsin	Mayo Clinic Health System in Eau Claire	Clairemont Campus Clinic 733 W. Clairemont Ave. Eau Claire, WI 54701	
North America	United States	Minnesota	Mayo Clinic Health System in Mankato	025 Marsh St., Mankato, MN 56001	
North America	United States	Wisconsin	Medical College of Wisconsin	8701 W Watertown Plank Rd, Milwaukee, WI 53226	
North America	United States	Florida	Mount Sinai Medical Center	4300 Alton Road Miami Beach, FL 33140	
North America	United States	Washington	Northwest Hospital & Medical Center	1550 N 115th St, Seattle, WA, 98133	
North America	United States	Illinois	Northwestern Lake Forest Hospital	1000 N. Westmoreland Road Lake Forest, IL 60045	

North America	United States	Illinois	Northwestern Lake Forest Hospital	Chicago, Illinois, 60611, United States	
North America	United States	Illinois	Northwestern Memorial HealthCare	259 E. Erie St. Chicago, IL 60611	
North America	United States	Illinois	Northwestern Memorial Hospital	251 E. Huron St. Chicago, IL, 60611	
North America	United States	Ohio	Ohio State University Comprehensive Cancer Center	460 W. 10th Avenue, Columbus, OH 43210	
North America	United States	Ohio	Ohio State University Wexner Medical Center	410 W. 10th Ave., Columbus, Ohio 43210	
North America	United States	Pennsylvania	Penn Medicine	800 Spruce Street, Philadelphia, PA 19107	
North America	United States	Pennsylvania	Perelman School of Medicine at the University of Pennsylvania	3400 Civic Center Boulevard, Building 421, Philadelphia, PA 19104	
North America	United States	Maryland	Regional Cancer Care Associates LLC	6410 Rockledge Drive, Suite 660 Bethesda MD 20817	
North America	United States	Illinois	Robert H. Lurie Comprehensive Cancer Center of Northwestern University	Galter Pavilion 675 N. St. Clair, 21st Floor Chicago, IL 60611	
North America	United States	Illinois	Rush University Medical Center	1620 W Harrison St, Chicago, IL 60612	

North America	United States	Washington	Seattle Cancer Care Alliance	825 Eastlake Ave. E, Seattle, WA 98109	
North America	United States	Maryland	Sidney Kimmel Comprehensive Cancer Center	401 North Broadway, Baltimore, MD 21231	
North America	United States	Pennsylvania	Sidney Kimmel Medical College	1025 Walnut St #100, Philadelphia, PA, 19107	
North America	United States	Missouri	Siteman Cancer Center	4921 Parkview Place, Saint Louis, MO 63110	
North America	United States	California	Stanford Cancer Center	875 Blake Wilbur Drive, Stanford, CA, 94305	
North America	United States	California	Stanford Health Care	300 Pasteur Drive, Stanford, CA 94305	
North America	United States	California	Stanford University School of Medicine	291 Campus Drive Li Ka Shing Building Stanford, CA 94305	
North America	United States	Washington	Swedish Medical Center	550 17th Ave Suite 540 Seattle, WA 98122	
North America	United States	Ohio	Taussig Cancer Institute	10201 Carnegie Ave., Cleveland, Ohio 44195	
North America	United States	Tennessee	Tennessee Oncology	120 Frank Martin Rd, Ste 102, Shelbyville,	

				TN 37160	
North America	United States	Tennessee	Tennessee Oncology	225 Big Station Camp Blvd., Suite 201, Gallatin, TN 37066	
North America	United States	Tennessee	Tennessee Oncology	300 Stonecrest Blvd., Ste. 400, Smyrna, TN 37167	
North America	United States	Tennessee	Tennessee Oncology	397 Wallace Road, Ste. 201, Nashville, TN 37211	
North America	United States	Tennessee	Tennessee Oncology	4323 Carothers Parkway Ste. 500 Franklin, TN 37067	
North America	United States	Tennessee	Tennessee Oncology	Chattanooga, Tennessee, 37404, United States	
North America	United States	Tennessee	Tennessee Oncology	Nashville, Tennessee, 37203, United States	
North America	United States	Utah	University of Utah	201 Presidents Circle, Salt Lake City, UT 84112	
North America	United States	Nevada	UC San Diego Health System	Las Vegas, Nevada, 89135, United States	
North America	United States	California	UCLAs Jonsson Comprehensive Cancer Center	8-684 Factor Building, Box 951781, Los Angeles, CA 90095	
North America	United States	California	UCSD Medical Center	9300 Campus Point Drive La	

				Jolla, CA 92037	
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 Diego School of Medicine	9500 Gilman Drive, La Jolla, CA, 92093	
North America	United States	California	University of California San Francisco	Box XXXX 550 16th St., Floor 4, San Francisco, CA 94143	
North America	United States	Illinois	University of Chicago	5801 South Ellis Avenue Chicago, Illinois 60637	
North America	United States	Illinois	University of Chicago Comprehensive Cancer Center	5758 S. Maryland Ave., Chicago IL 60637	
North America	United States	Iowa	University of Iowa Carver College of Medicine	451 Newton Road 200 Medicine Administration Building Iowa City, IA 52242	
North America	United States	Iowa	University of Iowa Hospitals and Clinics	200 Hawkins Drive, Iowa City, IA, 52242	
North America	United States	Kansas	University of Kansas	4000 Cambridge Street Kansas City, KS 66160	
North America	United States	Kansas	University of Kansas	Mail Stop 7004, 4330 Shawnee Mission	

				Parkway, Fairway, KS 66205	
North America	United States	Kansas	University of Kansas Hospital	3825 Cambridge St. Kansas City, KS 66160	
North America	United States	Kansas	University of Kansas Medical Center	2330 Shawnee Mission Pkwy, Westwood, KS 66205	
North America	United States	Kansas	University of Kansas Medical Center	4330 Shawnee Mission Parkway Fairway, KS 66205	
North America	United States	Kansas	University of Kansas Medical Center	Mail Stop 4033, 3901 Rainbow Boulevard, Kansas City, KS 66160	
North America	United States	Maryland	University of Maryland Baltimore	620 West Lexington Street, 4th Floor, Baltimore, Maryland, 21201	
North America	United States	Maryland	University of Greenebaum	22 S. Greene Street, Baltimore, MD 21201	
North America	United States	Maryland	University of Maryland Medical Center Corp	Baltimore, Maryland, 21201, United States	
North America	United States	Maryland	University of Maryland School of Medicine	655 W. Baltimore Street, Baltimore MD 21201	

North America	United States	Florida	University of Miami Health System	Miami, Florida, 33136, United States	
North America	United States	Florida	University of Miami Hospital	1400 NW 12th Avenue Miami, FL 33136	
North America	United States	Pennsylvania	University of Pennsylvania	Philadelphia, PA 19104	
North America	United States	Pennsylvania	University of Pittsburgh Medical Center	2000 Mary St. Pittsburgh, PA 15203	
North America	United States	Pennsylvania	University of Pittsburgh Medical Center	5230 Centre Ave. Pittsburgh, PA 15232	
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	New York	University of Rochester	265 Crittenden Blvd. Box CU420628, Suite: 1-250 Rochester NY, 14642	
North America	United States	Florida	University of South Florida	3702 Spectrum Blvd. Ste. 165, Tampa, FL 33612	
North America	United States	Utah	University of Utah School of Medicine	30 N. 1900 E Salt Lake City, Utah 84132	

North America	United States	Virginia	University of Virginia	Charlottesville, Virginia, 22903, United States	
North America	United States	Virginia	University of Virginia	P.O. Box 800392, Charlottesville, VA 22908	
North America	United States	Virginia	University of Virginia Medical Center	1215 Lee Street, Charlottesville, VA 22903	
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	5115 Centre Avenue, Pittsburgh, PA 15232	
North America	United States	Washington	UW Medical Center	Seattle, Washington, 98109, United States	
North America	United States	Tennessee	Vanderbilt University Medical Center	1211 Medical Center Drive, Nashville, TN 37232	
North America	United States	Tennessee	Vanderbilt University Medical Center	1500 21st Ave South, Suite 1506, Nashville, TN 37212	
North America	United States	Tennessee	Vanderbilt-Ingram Cancer Center	2220 Pierce Avenue, Nashville, TN 37232	
North America	United States	Maryland	Warren Grant Magnuson Clinical Center	10 Center Drive, Bethesda, MD 20892	

North America	United States	Missouri	Washington University Physicians	4921 Parkview Place 6th Floor, Suites A & B, 12th Floor, Suite A St. Louis, MO 63110	
North America	United States	Missouri	Washington University School of Medicine	660 S. Euclid Ave., St. Louis, MO 63110	
North America	United States	Michigan	Wayne State University	42 W. Warren Ave., 1st Floor Lobby Detroit, MI 48201	
North America	United States	Michigan	Wayne State University Physician Group	26400 W. 12 Mile Rd., Suite 111 Southfield, MI 48034	
North America	United States	Pennsylvania	Children's Hospital of Philadelphia	3401 Civic Center Blvd., Philadelphia, PA, 19104	
North America	United States	Florida	Cleveland Clinic of Florida	2950 Cleveland Clinic Boulevard Weston, Florida 33331	
North America	United States	New York	James P. Wilmot Cancer Center	90 Crittenden Blvd. Rochester, NY 14642	
North America	United States	New York	Mount Sinai Hospital	1 Gustave L. Levy Place, New York, NY, 10029	
North America	United States	Maryland	National Institutes of Health Clinical Center	10 Center Drive, Bethesda, MD 20892	

North America	United States	California	Ronald Reagan UCLA Medical Center	1260 15th Street Ste 602B Santa Monica, CA 90404	
North America	United States	California	Ronald Reagan UCLA Medical Center	757 Westwood Plaza Los Angeles, CA 90095	
North America	United States	Pennsylvania	Sidney Kimmel Cancer Center at Thomas Jefferson University	Bluemle Life Sciences Building, 233 South 10th Street, Suite 1050, Philadelphia, PA 19107	
North America	United States	California	Stanford University	3165 Porter Drive Palo Alto, CA 94304	
North America	United States	California	Stanford University	450 Serra Mall, Stanford, CA 94305	
North America	United States	New York	The Tisch Cancer Institute	One Gustave L. Levy Place, Box 1128, New York, NY, 10029	
North America	United States	Pennsylvania	Thomas Jefferson University Hospitals	132 South 10th Street, Philadelphia, PA 19107	
North America	United States	Florida	University of Miami Sylvester Comprehensive Cancer Center	1475 N.W. 12th Avenue, Miami, Florida 33136	
North America	United States	New York	Weill Cornell Medical College	1305 York Ave, 5 th Floor New York, NY 10021	

North America	United States	Ohio	Cleveland Clinic Cancer Center	1125 Aspira Court, Mansfield, OH 44906	
North America	United States	Ohio	Fairview Hospital	18101 Lorain Ave. Cleveland, Ohio 44111	
North America	United States	New Jersey	Hackensack Meridian Health	Neptune, NJ, 07753-6807	
North America	United States	Ohio	Hillcrest Cancer Center	6780 Mayfield Rd. Mayfield Heights, Ohio 44124	
North America	United States	Wisconsin	Mayo Clinic Health System – Franciscan Healthcare	700 West Ave. S., La Crosse, WI 54601	
North America	United States	Florida	Memorial Hospital Jacksonville	3625 University Blvd. S, Jacksonville, FL 32216	
North America	United States	Ohio	North Coast Cancer Sandusky	417 Quarry Lakes Dr. Sandusky , Ohio 44870	
North America	United States	Illinois	Northwestern Medicine Cancer Center Delnor	304 Randall Road Geneva, IL 60134	
North America	United States	Illinois	Northwestern Medicine Cancer Center Warrenville	4405 Weaver Parkway Warrenville, IL 60555	
North America	United States	Pennsylvania	Ruth & Raymond Perelman Center for Advanced Medicine	Philadelphia, Pennsylvania, 19104, United States	
North America	United States	Missouri	Saint Lukes Cancer Institute LLC	4321 Washington St Ste 4000,	

				Kansas City, MO, 64111	
North America	United States	Tennessee	Sarah Cannon Cancer Center	3441 Dickerson Pike | Nashville, TN 37207	
North America	United States	Illinois	Silver Cross Hospital	1301 Copperfield Ave. Joliet, IL 60432	
North America	United States	Utah	South Jordan Health Center	5126 W. Daybreak Parkway, South Jordan, UT 84009	
North America	United States	Ohio	South Pointe Hospital	20000 Harvard Rd., Warrensville Heights, Ohio 44122	
North America	United States	California	Stanford University Medical Center	300 Pasteur Drive, Stanford, CA 94305	
North America	United States	California	Stanford University Medical Center	3172 Porter Drive Palo Alto, CA 94304	
North America	United States	Ohio	Strongsville Family Health and Surgery Center	16761 South Park Center, Strongsville, Ohio 44136	
North America	United States	Maryland	The Center for Cancer Research	National Cancer Institute, Building 31, Room 3A11 31, Center Drive Bethesda, Maryland 20892	

North America	United States	California	UCLA Hematology Oncology	10833 Le Conte Ave., 60-054 Los Angeles, CA 90095	
North America	United States	California	UCLA Medical Hematology and Oncology	100 UCLA Medical Plaza, Suite 550 & 555, Los Angeles, CA 90095	
North America	United States	Illinois	University of Chicago Medicine Center for Advanced Care	14290 S. La Grange Rd Orland Park, IL 60462	
North America	United States	Iowa	University of Iowa Health Care	200 Hawkins Drive, Iowa City, IA 52242, United States	
North America	United States	Virginia	UVA Cancer Center	Box 800334, Charlottesville, VA 22908	
North America	United States	Tennessee	Vanderbilt Breast Center at One Hundred Oaks	719 Thompson Lane, Nashville, TN 37204.	
North America	United States	Tennessee	Vanderbilt-Ingram Cancer Center Franklin	324 Cool Springs Boulevard Franklin, TN, 37067	
North America	United States	Ohio	Wooster Family Health & Surgery Center	1740 Cleveland Rd. Wooster, Ohio 44691	
Middle East and Africa	Israel	Haifa	Israel Institute of Technology	Ullmann Building, Technion City, Haifa 3200003	
Middle East	Israel	Haifa	Rambam Health	P.O.B. 9602	

and Africa			Care Campus	Haifa 31096 Israel	
North America	Canada	Nova Scotia	Dalhousie University	Halifax, Nova Scotia, Canada, B3H 4R2	
North America	Canada	Quebec	Hospital of the Child Jesus	1401, 18e Rue, Quebec (Quebec), G1J 1Z4	
North America	Canada	Quebec	Maisonneuve-Rosemont Hospital	5305, boul. de l'Assomption, Montréal (Québec) H1T 2M4	
North America	Canada	Nova Scotia	Nova Scotia Health Authority	1276 South Park Street, Halifax, NS, B3H 2Y9	
North America	Canada	Ontario	Ottawa Hospital Research Institute	501 Smyth Box 511, Ottawa, ON, K1H 8L6	
North America	Canada	Quebec	University Affiliated Hospital of Quebec	1401 18e Rue, Quebec, QC, G1J 1Z4, Canada	
North America	Canada	Ontario	University Health Network	R. Fraser Elliott Building, 1st Floor 190 Elizabeth St. Toronto, ON M5G 2C4	
North America	Canada	British Columbia	The University of British Columbia	2329 West Mall Vancouver, BC Canada V6T 1Z4	
North America	Canada	Manitoba	University of Manitoba	715 McDermot Ave Winnipeg,	

				MB R3E 3P4	
North America	Canada	Ontario	University of Ottawa	75 Laurier Avenue East Ottawa ON K1N 6N5	
North America	Canada	Ontario	University of Toronto	27 King's College Circle Toronto, Ontario M5S 1A1 Canada	
North America	Canada	British Columbia	Vancouver Coastal Health	803 West 12th Avenue, Vancouver, BC V5Z 1M9	
Europe	United Kingdom	England	Addenbrooke's Hospital	Hills Rd, Cambridge, CB2 0QQ, United Kingdom	
Europe	Germany	Hamburg	Asklepios Klinik St Georg	Lohmühlenstrabe 5, 20099 Hamburg	
Europe	Spain	Madrid	Autonomous University of Madrid	Ciudad Universitaria de Cantoblanco · 28049 Madrid	
Europe	United Kingdom	England	Bristol Haematology and Oncology Centre	Horfield Road, Bristol, BS2 8ED	
Europe	Belgium	Brussels	Catholic University of Louvain	Tour 54 Claude Bernard +1, Avenue Hippocrate 54-55, bte B1.54.01, 1200 Bruxelles	
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Europe	Germany	Schleswig-	Christian-	Brunswiker	

		Holstein	Albrechts-University of Kiel	Straße 16-22, 24105	
Europe	Croatia	Brod-Posavina	Dr Josip Bencevic General Hospital	Andrew Štampara 42, HR-35000 Slavonski Brod	
Europe	Germany	Saxony	Dresden University of Technology	01307 Dresden	
Europe	Italy	Lombardy	Fondazione Centro San Raffaele del Monte Tabor	Olgettina 60, 20132 Milano, Italia	
Europe	United Kingdom	England	Guy's and St Thomas' NHS Foundation Trust	Great Maze Pond London SE1 9RT	
Europe	France	Ile de France	Hospital Avicenne	125 rue de Stalingrad 93 000 Bobigny	
Europe	Spain	Catalonia	Hospital del Mar	Passeig Marítim 25-29 Barcelona 08003	
Europe	Spain	Madrid	Hospital Gregorio Maranon	C/ Doctor Esquerdo, 46 28007 Madrid	
Europe	Spain	Catalonia	University Hospital of Girona Dr Josep Trueta	Avenue of France s / n17007 Girona	
Europe	Spain	Catalonia	Hospital Germans Trias i Pujol	Carretera de Canyet s/n. 08916 Badalona	
Europe	Spain	Catalonia	Hospital Universitari Quiron Dexeus	Street Sabino Arana 5-19 - Floor 1 08028 Barcelona Barcelona	
Europe	Spain	Andalusia	University Hospital of Virgen del Rocio	Edificio de Gobierno, planta baja	

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Europe	Spain	Catalonia	Instituto Oncologico Baselga	Plaza Alfonso Comín, 5 08023 Barcelona	
Europe	Italy	Lombardy	Istituto Clinico Humanitas	Via Manzoni, 56 - 20089 Rozzano (Milano	
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Europe	Sweden	Scania	Lund University Hospital	Lund, Scania, Sweden, 22185	
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Europe	France	Brittany	Rennes University Hospital	2 rue Henri Le Guilloux 35033 Rennes cedex 9	
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Europe	United Kingdom	England	Sarah Cannon Research Institute UK Ltd	London, England, W1G6AD, United Kingdom	
Europe	United Kingdom	England	St. Bartholomew's Hospital	London, England, EC1A7BE, United Kingdom	
Europe	Germany	Saxony	University Hospital Carl Gustav Carus Dresden	Fetscherstraße 74, 01307 Dresden	
Europe	United Kingdom	England	University Hospitals Bristol and Weston NHS Foundation Trust	Bristol, England, BS28ED, United Kingdom	
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Europe	Spain	Catalonia	University of Barcelona	Gran Via de les Corts Catalanes, 585,	

				08007, Barcelona	
Europe	Italy	Emilia-Romagna	University of Bologna	S.Orsola-Malpighi - Via Massarenti, 9 - 40138 Bologna	
Europe	Netherlands	Groningen	University of Groningen	Antonius Deusinglaan 1, 9713 AV Groningen	
Europe	Germany	Baden-Wuerttemberg	University of Heidelberg	Im Neuenheimer Feld 270 D-69120 Heidelberg	
Europe	United Kingdom	England	The University of Manchester	Oxford Rd, Manchester, M13 9PL	
Europe	Germany	North Rhine-Westphalia	University of Munster	Schlossplatz 2, 48149	
Europe	France	Brittany	University of Rennes I	2 rue du Thabor - CS 46510, 35042 Rennes CEDEX	
Europe	France	Ile de France	University Paris 7 - Denis Diderot	U698 Inserm - CHU Xavier Bichat, 16, rue Henri-Huchard - B.P. 416, 75877 PARIS CEDEX 18	
Europe	Sweden	Uppsala	Uppsala University	Akademiska sjukhuset, Ing. 40, 5 tr 75185 Uppsala	
Europe	Austria	Vienna	Vienna General Hospital	AKH Vienna, 1090 Vienna, Währinger belt 18-20	
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Europe	Germany	North Rhine-Westphalia	KMT-Zentrum	Albert-Schweitzer-Campus 1, Gebäude A12(ehemals: Domagkstraße 9a), 48149 Münster	
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North America	Canada	Ontario	The Ottawa Hospital Cancer Centre	Ottawa, Ontario, K1H8L6, Canada	
North America	United States	Illinois	Northwestern Medicine Kishwaukee Hospital Cancer Center	10 Health Services Drive DeKalb, IL 60115	
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Key Trial Events (78)

Event Date	Event Brief	Event Type	Source
14 Apr 2024	The Cost-effectiveness of Axicabtagene Ciloleucel Versus Standard of Care as Second-line Therapy in Patients with Large B-cell Lymphoma in Italy Trial results updated	Results	https://ebmt2024.abstractserver.com/program/#/details/presentations/1304
05 Apr 2024	Novel Tumor Gene Expression Signatures Predictive of Outcome in Large B Cell Lymphoma Treated with Car T Cell Therapy (Axicabtagene Ciloleucel) Trial results are updated	Results	https://www.abstractsonline.com/pp8/#!/20272/presentation/10384
26 Mar 2024	Shanghai Fosun Pharmaceutical Announces Annual Results Announcement for the Year Ended 31 December 2023	Trial Update	https://www1.hkexnews.hk/listedco/listconews/sehk/2024/0326/2024032602655.pdf
07 Mar 2024	Clinical Trial Update Trial Result update	Results	https://classic.clinicaltrials.gov/ct2/show/results/NCT03391466
21 Dec 2023	U.S. FDA Approves Label Update for Kite’s Yescarta CAR T-Cell Therapy to Include Overall Survival Data Results Updated	Results	https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/us-fda-approves-label-update-for-kites-yescarta-car-tcell-

			therapy-to-include-overall-survival-data
11 Dec 2023	Analyses of Kite's Yescarta CAR T-Cell Therapy Support Curative Potential in Patients With Non-Hodgkin Lymphomas Trial subgroup analysis, conclusion updated; followup group analysis presented at ash conference	Results;Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/analyses-of-kites-yescartacar-t-cell-therapy-support-curative-potential-in-patients-with-non-hodgkin-lymphomas
11 Dec 2023	Studies Highlight Both Novel Treatments and Enduring Value of Older Approaches	Trial Update	https://www.prnewswire.com/news-releases/studies-highlight-both-novel-treatments-and-enduring-value-of-older-approaches-302010757.html
09 Dec 2023	Improved Overall Survival with Axicabtagene Ciloleucel Vs Standard of Care in Second-line Large B-cell Lymphoma among the Elderly: A Subgroup Analysis of ZUMA-7 Trial Subgroup Analysis results updated	Results	https://ash.confex.com/ash/2023/webprogram/Paper173873.html
09 Dec 2023	An Inflammatory Biomarker Signature Reproducibly Predicts CAR-T Treatment Failure in Patients with Aggressive Lymphoma across the Zuma Trials Cohorts Trial pooled results updated.	Pooled Results	https://ash.confex.com/ash/2023/webprogram/Paper173798.html
09 Dec 2023	Statistical Challenges from Trials of Potentially Curative Treatments: Validation of Cure Assumptions When Analyzing Zuma-7 Follow-up Data of Axi-cel and Standard of Care Therapy Trial results updated	Results	https://ashpublications.org/blood/article/142/Supplement%201/6899/500947/Statistical-Challenges-from-Trials-of-Potentially
07 Dec 2023	Sarah Cannon Research Institute to Present Latest Research Insights at the 2023 ASH Annual Meeting & Exposition	Trial Update	https://www.businesswire.com/news/home/20231207970384/en/Sarah-Cannon-Research-Institute-to-Present-Latest-Research-Insights-at-the-2023-ASH-Annual-Meeting-Exposition
02 Nov 2023	Gilead and Kite Oncology Present Data Demonstrating Car T-cell Therapy	Trial Update	https://www.gilead.com/news-and-press/press-room/press-

	Survival Benefit and Showcasing Latest Advances in Blood Cancer Portfolio at ASH 2023		releases/2023/11/gilead-and-kite-oncology-present-data-demonstrating-car-t-cell-therapy-survival-benefit-and-showcasing-latest-advances-in-blood-cancer-portfolio-at-as
05 Oct 2023	Axicabtagene Ciloleucel Results in High Response Rates and Durable Remissions as a Second-Line Treatment for Large B Cell Lymphoma for ASCT	Trial Update	https://www.esmo.org/oncology-news/axicabtagene-ciloleucel-results-in-high-response-rates-and-durable-remissions-as-a-second-line-treatment-for-patients-with-relapsed-or-refractory-large-b-cell-lymphoma-ineligible-for-asct
06 Sep 2023	Cost-effectiveness of the Chimeric Antigen Receptor (Car) T-cell Treatments, Lisocabtagene Maraleucel (Liso-cel) Versus Axicabtagene Ciloleucel (Axi-cel), as Second-line (2l) Treatment of Large B-cell Lymphoma (Lbcl) Trial results updated	Pooled Results	https://clml-soho2023.elsevierdigitaledition.com/index.html
03 Aug 2023	Gilead Sciences Announces Second Quarter 2023 Financial Results	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2023/8/gilead-sciences-announces-second-quarter-2023-financial-results
18 Jul 2023	Yikaida CAR-T Cell Therapy Approved as a Second-line Therapy for New Indication	Trial Update	https://www.prnewswire.com/news-releases/yikaida-car-t-cell-therapy-approved-as-a-second-line-therapy-for-new-indication-301880444.html
13 Jun 2023	Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard of Care in Relapsed/Refractory Large B-cell Lymphoma Trial results updated.	Results	https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
13 Jun 2023	Circulating Tumor Dna (Ctdna) by Clonoseq to Monitor Residual Disease after Axicabtagene Ciloleucel (Axi-cel) in Large B-cell Lymphoma (Lbcl) Trial	Pooled Results	https://onlinelibrary.wiley.com/doi/10.1002/hon.3164_234

	pooled results updated.		
06 Jun 2023	Kite's Yescarta CAR T-cell Therapy Demonstrates Significantly Longer Overall Survival Versus Standard of Care as Treatment of Large B-cell Lymphoma Results updated	Results	https://www.gilead.com/news-and-press/press-room/press-releases/2023/6/kites-yescarta-car-t-cell-therapy-demonstrates-significantly-longer-overall-survival-versus-standard-of-care-as-initial-treatment-of-relapsedrefrac
02 Jun 2023	Primary Overall Survival Analysis of the Phase 3 Randomized Zuma-7 Study of Axicabtagene Ciloleucel Versus Standard-of-care Therapy in Relapsed/refractory Large B-cell Lymphoma Trial results updated.	Results	https://meetings.asco.org/abstracts-presentations/220014
02 Jun 2023	Circulating Tumor DNA (ctDna) by ClonoSEQ to Monitor Residual Disease after Axicabtagene Ciloleucel (Axi-cel) in Large B-cell Lymphoma (LBCL) Trial pooled results updated	Pooled Results	https://meetings.asco.org/abstracts-presentations/220315
17 May 2023	Gilead and Kite Oncology to showcase advances across the pipeline aiming to address unmet needs in cancer care at ASCO 2023	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2023/5/gilead-and-kite-oncology-to-showcase-advances-across-the-pipeline-aiming-to-address-unmet-needs-in-cancer-care-at-asco-2023
27 Apr 2023	Gilead Sciences announces first quarter 2023 financial results	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2023/4/gilead-sciences-announces-first-quarter-2023-financial-results
23 Apr 2023	Outcomes of Subsequent Anti-lymphoma Therapies in Patients with Relapsed/Refractory Large B-cell Lymphoma (LBCL) Treated with Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC; ZUMA-7). Trial results updated	Results	https://ebmt2023.abstractserver.com/program/#/details/presentations/790
23 Apr 2023	Association of Metabolic Tumor	Results	https://ebmt2023.abstractserv

	Volume (Mtv) and Clinical Outcomes in Second-line Relapsed/Refractory Large B-cell Lymphoma Following Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care (Soc) Therapy in Zuma-7 Trial results updated.		er.com/program/#/details/presentations/791
22 Apr 2023	Outcomes of Subsequent Anti-lymphoma Therapies in Patients with Relapsed/Refractory Large B-cell Lymphoma (LBCL) Treated with Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC; ZUMA-7) Trial results updated	Results	https://ebmt2023.abstractserver.com/program/#/details/presentations/790
23 Mar 2023	Kite's yescarta (axicabtagene ciloleucel) first car t-cell therapy to receive health canada authorization for use in second-line large b-cell lymphoma	Trial Update	https://www.newswire.ca/news-releases/kite-s-yescarta-r-axicabtagene-ciloleucel-first-car-t-cell-therapy-to-receive-health-canada-authorization-for-use-in-second-line-large-b-cell-lymphoma-876026171.html
21 Mar 2023	Kite’s Yescarta CAR T-cell therapy demonstrates a statistically significant improvement in overall survival for initial treatment of relapsed/refractory large B-cell lymphoma	Results;Trial Update	https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract
15 Feb 2023	Outcomes of Subsequent Anti-Lymphoma Therapies in Patients (Pts) with Large B-Cell Lymphoma (LBCL) Treated with Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC) in the Second-Line (2L) Zuma-7 Study Trial results updated.	Results	https://astct-29-s2.elsevierdigitaledition.com/
15 Feb 2023	Association of Metabolic Tumor Volume (MTV) and Clinical Outcomes in Second-Line (2L) Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Following Axicabtagene Ciloleucel (Axi-Cel) Versus Standard-of-Care (SOC)	Results	https://astct-29-s2.elsevierdigitaledition.com/

	Therapy in Zuma-7 Trial results updated.		
22 Dec 2022	Yescarta now approved in Japan for initial treatment of relapsed/refractory large B-cell lymphoma	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/yescarta-now-approved-in-japan-for-initial-treatment-of-relapsedrefractory-large-b-cell-lymphoma
11 Dec 2022	Time to CAR T-cell Therapy may impact outcomes for patients with Relapsed/Refractory Large B-cell Lymphoma in new CIBMTR analysis	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/time-to-car-t-cell-therapy-may-impact-outcomes-for-patients-with-relapsedrefractory-large-b-cell-lymphoma-in-new-cibmtr-analysis
11 Dec 2022	Body of Evidence Grows From ZUMA-7 Study Supporting Initial Treatment With Kite's Yescarta CAR T-cell Therapy for Patients With Relapsed or Refractory Large B-cell Lymphoma	Results	https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/body-of-evidence-grows-from-zuma-7-study-supporting-initial-treatment-with-kites-yescarta-car-t-cell-therapy-for-patients-with-relapsed-or-refractor
11 Dec 2022	Outcomes of Subsequent Anti-Lymphoma Therapies in Patients (Pts) With Large B-Cell Lymphoma (LBCL) Treated With Axicabtagene Ciloleucel (Axi-Cel) or Standard of Care (SOC) in the Second-Line (2L) ZUMA-7 Study. Trial results updated.	Results	https://ash.confex.com/ash/2022/webprogram/Paper158303.html
10 Dec 2022	Association of Metabolic Tumor Volume (MTV) and Clinical Outcomes in Second-Line (2L) Relapsed/Refractory (R/R) Large B-Cell Lymphoma (LBCL) Following Axicabtagene Ciloleucel (Axi-Cel) Versus Standard-of-Care (SOC) Therapy in ZUMA-7. Trial results updated.	Results	https://ash.confex.com/ash/2022/webprogram/Paper158492.html
10 Dec 2022	Matching-adjusted Indirect Comparison	Pooled Results	https://ashpublications.org/bl

	(MAIC) of Lisocabtagene Maraleucel (Liso-cel) Versus Axicabtagene Ciloleucel (Axi-cel) for Second-line (2L) Treatment of Patients (Pt) with Refractory/Early Relapsed (R/R) Large B-cell Lymphoma (LBCL) Trial pooled results updated		ood/article/140/Supplement%201/4655/490968/Matching-Adjusted-Indirect-Comparison-MAIC-of
21 Nov 2022	Bristol Myers Squibb data at ASH 2022 highlight innovative therapeutic platforms across a range of blood diseases	Trial Update	https://news.bms.com/news/corporate-financial/2022/Bristol-Myers-Squibb-Data-at-ASH-2022-Highlight-Innovative-Therapeutic-Platforms-Across-a-Range-of-Blood-Diseases/default.aspx
03 Nov 2022	Gilead and Kite Oncology demonstrate transformative impact of cell therapy and promise of blood cancer portfolio at ASH 2022	Trial Update	https://www.businesswire.com/news/home/20221103005748/en/Gilead-and-Kite-Oncology-Demonstrate-Transformative-Impact-of-Cell-Therapy-and-Promise-of-Blood-Cancer-Portfolio-at-ASH-2022
17 Oct 2022	Kite's Yescarta first CAR T-cell therapy to receive European Marketing Authorization for use in second-line diffuse large B-cell lymphoma and high-grade B-cell lymphoma	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2022/10/kites-yescarta-first-car-t-cell-therapy-to-receive-european-marketing-authorization-for-use-in-second-line-diffuse-large-b-cell-lymphoma-and-high-gra
16 Sep 2022	Kite's CAR T-cell therapy Yescarta first in Europe to receive positive CHMP opinion for use in second-line diffuse large b-cell lymphoma and high-grade b-cell lymphoma	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2022/9/kites-car-t-cell-therapy-yescarta-first-in-europe-to-receive-positive-chmp-opinion-for-use-in-second-line-diffuse-large-b-cell-lymphoma-and-high-gra
18 Jul 2022	Novotech and Endpoints Present "Evolution of Cell & Gene Therapy in China: The Case for Universal CAR-T"	Trial Update	https://www.acnnewswire.com/press-release/english/76528/

11 Jun 2022	Grade ≥3 treatment-emergent adverse events occurred in 94% and 82% of axicabtagene ciloleucel and standard-of-care subjects, respectively. Grade 5 treatment-related adverse events occurred in 0 and 1 subject of axicabtagene ciloleucel and standard-of-care subjects, respectively. Results updated	Results	https://library.ehaweb.org/eha/2022/eha2022-congress/357075/anna.sureda.clinical.and.patient-reported.outcomes.in.a.phase.3.study.of.html?f=menu%3D6%2Abrowseby%3D8%2Asortby%3D2%2Amedia%3D3%2Ace_id%3D2233%2Aot_id%3D26858%2Amarker%3D1751
08 Jun 2022	Precision BioSciences provides update on allogeneic CAR T programs and path forward with its lead PBCAR0191 candidate for CAR T relapsed patient population	Trial Update	https://investor.precisionbiosciences.com/news-releases/news-release-details/precision-biosciences-provides-update-allogeneic-car-t-programs
04 Jun 2022	Clinical and Patient (Pt)-reported Outcomes (PROs) in a Phase 3, Randomized, Open-label Study Evaluating Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care (SOC) Therapy in Elderly Pts with Relapsed/Refractory (R/R) Large B-cell Lymphoma (LBCL; Zuma-7) Results updated	Results	https://meetings.asco.org/abstracts-presentations/209923
04 Jun 2022	Sub-analyses of Landmark ZUMA-7 Trial Reinforce Yescarta CAR T-cell Therapy Superiority Over Standard of Care (SOC) as Initial Treatment for Patients With Relapsed or Refractory Large B-cell Lymphoma (LBCL) Results updated	Results	https://www.businesswire.com/news/home/20220604005006/en/Sub-analyses-of-Landmark-ZUMA-7-Trial-Reinforce-Yescarta%C2%AE-CAR-T-cell-Therapy-Superiority-Over-Standard-of-Care-SOC-as-Initial-Treatment-for-Patients-With-Relapsed-or-Refractory-Large-B-cell-Lymphoma-LBCL
04 Jun 2022	Association of Pretreatment (Pretx) Tumor Characteristics and Clinical Outcomes Following Second-line (2l) Axicabtagene Ciloleucel (Axi-cel) Versus Standard of Care (SOC) in Patients (Pts) with Relapsed/Refractory	Results	https://meetings.asco.org/abstracts-presentations/210240

	(R/R) Large B-cell Lymphoma (LBCL) Results updated		
04 Jun 2022	Quality-adjusted Time Without Symptoms or Toxicities (Q-TWiST) Analysis of ZUMA-7, a Randomized Controlled Trial of Axicabtagene Ciloleucel Versus Standard of Care for Second-line Large B-cell Lymphoma Results updated.	Results	https://meetings.asco.org/abstracts-presentations/209948
17 May 2022	Gilead and Kite Oncology to Highlight Advances Supporting New Innovations in Cancer Care at the ASCO Annual Meeting	Trial Update	https://www.businesswire.com/news/home/20220517005997/en
16 May 2022	Primary Analysis of ZUMA7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-Cel) versus StandardofCare (SOC) Therapy in Patients (Pts) with Relapsed/ Refractory (R/R) Large B-Cell Lymphoma (LBCL) Trial results updated	Results	https://www.cell.com/molecular-therapy-family/molecular-therapy/pdf/S1525-0016(22)00246-5.pdf
26 Apr 2022	Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-Cel) Versus Standard of Care (SOC) Therapy in Patients with Relapsed/Refractory Large B-Cell Lymphoma Results updated.	Results	https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19266
26 Apr 2022	Cost-Effectiveness of Axicabtagene Ciloleucel As Second-Line Therapy for Patients Large B-Cell Lymphoma (LBCL) in the United States. Trial results updated.	Results	https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/20530
25 Apr 2022	Patient-reported Outcomes (PROS) in Zuma-7, a Phase 3, Randomized, Open-label Study Evaluating the Efficacy of Axicabtagene Ciloleucel (AXI-CEL) Versus Standard-of-care (SOC) Therapy in Patients with Relapsed/Refractory Large B-cell Lymphoma (LBCL) Trial results updated.	Results	https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19351
11 Apr 2022	Gender bias in the association of pre-treatment cytokine signatures with	Results	https://www.abstractsonline.com/pp8/#!/10517/presentatio

	response and survival in B cell lymphoma patients treated with anti-CD19 CAR T-cell therapy Results updated		n/12678
10 Apr 2022	Product attributes of axicabtagene ciloleucel (axi-cel) that associate differentially with efficacy and toxicity in second-line large B-cell lymphoma Trial results updated	Results	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146
23 Mar 2022	Primary Analysis of Zuma 7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel(axi-Cel) Versus Standard of Care(soc) Therapy in Patients With Relapsed/Refractory Large B-Cell Lymphoma. Trial results updated.	Results	https://ebmt2022.abstractserver.com/program/#/details/presentations/855
22 Mar 2022	Superiority of Axicabtagene Ciloleucel (Axi-cel) in Second-line (2l) Large B-cell Lymphoma (Lbcl) in the Elderly Trail results updated.	Results	https://ebmt2022.abstractserver.com/program/#/details/presentations/819
19 Mar 2022	Patient-reported Outcomes in Zuma-7, a Phase 3, Randomized, Open-label Study Evaluating the Efficacy of Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care Therapy in Relapsed/Refractory Large B-cell Lymphoma. Results updated.	Results	https://ebmt2022.abstractserver.com/program/#/details/presentations/805
19 Mar 2022	In addition to meaningfully improving key clinical endpoints, axicel is a cost-effective treatment option that can address an important unmet need Trial results updated	Results	https://ebmt2022.abstractserver.com/program/#/details/presentations/1024
03 Jan 2022	Immunotherapy with genetically modified immune cells increases survival of patients with aggressive B lymphoma who do not respond to chemotherapy	Trial Update	https://idibell.cat/en/2021/12/immunotherapy-with-genetically-modified-immune-cells-increases-survival-of-patients-with-aggressive-b-lymphoma-who-do-not-respond-to-chemotherapy/
31 Dec 2021	Third Quarter 2020 Results	Results	http://investors.gilead.com/st

	Presentation, Oct 2020 Study data expected in 2021.		atic-files/7db4987f-930d-4b18-877e-0c75d5e34c0d
12 Dec 2021	Primary Analysis of Zuma-7: A Phase 3 Randomized Trial of Axicabtagene Ciloleucel (Axi-cel) Versus Standard-of-care Therapy in Patients with Relapsed/Refractory Large B-cell Lymphoma results updated	Results	https://ash.confex.com/ash/2021/webprogram/Paper148039.html
11 Dec 2021	New studies highlight how immunotherapies are transforming care for blood cancers	Trial Update	https://www.prnewswire.com/news-releases/new-studies-highlight-how-immunotherapies-are-transforming-care-for-blood-cancers-301442599.html
09 Dec 2021	John Theurer Cancer Center investigators present pioneering research at the American Society of Hematology Annual Conference	Trial Update	https://www.prnewswire.com/news-releases/john-theurer-cancer-center-investigators-present-pioneering-research-at-the-american-society-of-hematology-annual-conference-301441326.html
04 Nov 2021	Gilead and Kite Oncology demonstrate broad leadership in cell therapy and expanding blood cancer pipeline	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2021/11/gilead-and-kite-oncology-demonstrate-broad-leadership-in-cell-therapy-and-expanding-blood-cancer-pipeline
30 Sep 2021	Kite submits supplemental biologics license application to U.S. Food and Drug Administration for earlier use of Yescarta in large B-cell lymphoma	Trial Update	https://www.kitepharma.com/news/press-releases/2021/9/kite-submits-supplemental-biologics-license-application-to-us-food-and-drug-administration-for-earlier-use-of-yescarta-in-large-bcell-lymphoma
04 Aug 2021	University of Kansas Medical Center: Early trial results indicate Yescarta CAR-T therapy improves survival for adults who relapse from large B-cell lymphoma Result added	Results	https://www.kumc.edu/news-listing-page/zuma-7.html

29 Jul 2021	Gilead Sciences announces second quarter 2021 financial results	Trial Update	https://www.gilead.com/news-and-press/press-room/press-releases/2021/7/gilead-sciences-announces-second-quarter-2021-financial-results
30 Jun 2021	The Virtual 39th Annual JP Morgan Healthcare Conference Study data read-out expected in first half of 2021	Results	http://investors.gilead.com/static-files/da2a6be6-1c7a-4769-aa73-8f00408c91a3 (Slide 21)
28 Jun 2021	Kite announces Yescarta CAR T-cell Therapy improved event-free survival by 60% over chemotherapy Plus Stem Cell Transplant in Second-Line Relapsed or Refractory Large B-cell Lymphoma Interim Result added	Interim Results	https://www.gilead.com/news-and-press/press-room/press-releases/2021/6/kite-announces-yescarta-car-tcell-therapy-improved-eventfree-survival-by-60-over-chemotherapy-plus-stem-cell-transplant-in-secondline-relapsed-or
31 Dec 2020	Fourth Quarter 2019 Earnings Results Presentation February 2020 Phase 3 study data expected in second half of 2020.	Results	http://investors.gilead.com/static-files/36dc002c-bce8-4242-b087-f4e388d6b606 (Slide no: 08)
01 Nov 2019	Clinical Trial Registry Update Trial status updated Trial enrollment status reported	Enrollment Status;Trial Status;Trial Update	• https://clinicaltrials.gov/ct2/history/NCT03391466?A=36&B=38&C=Side-by-Side#StudyPageTop
18 Oct 2017	New gene-altering treatment offered for blood cancers	Trial Update	https://siteman.wustl.edu/new-gene-altering-treatment-offered-blood-cancers/
19 Oct 2016	Kite Pharma Provides Update on KTE-C19 and Launch Preparedness at Investor Day	Trial Update	http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338
19 Oct 2016	Kite Pharma provides update on KITE-796 clinical development program at Investor Day	Trial Update	http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338
19 Oct 2016	Kite Pharma provides update on KITE-585 clinical development program at Investor Day	Trial Update	http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338

19 Oct 2016	Kite Pharma provides update on KITE-718 clinical development program at Investor Day	Trial Update	http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338
19 Oct 2016	Kite Pharma provides update on KITE-439 clinical development program at Investor Day	Trial Update	http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338
26 Mar 2015	Kite Pharma Reports Full-Year and Fourth Quarter 2014 Financial Results	Trial Update	http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=903451

Insights (1)

Published Date	Headline
13-Apr-2018	Celgene/bluebird indicate myeloma CAR-T confirmatory study to not allow crossover from control arm, source says

History of changes

Modified Date	Update Type	Description	From Data	To Data	Source Date	Source Type	Source
19-Apr-2024	Trial Result	Trial Results Updated			14-Apr-2024	Conferences	https://ebmt2024.abstractserver.com/program/#/details/presentations/1304
19-Apr-2024	Study Design/ Trial Description	Trial Description Updated			14-Apr-2024	Conferences	https://ebmt2024.abstractserver.com/program/#/details/presentations/1304
19-Apr-2024	Study Design/ Trial Description	Study Design Updated	Randomized, Active control, Parallel Assignment, Open-label, Treatment, Confirmatory, Multi-	Randomized, Active control, Parallel Assignment, Open-label, Treatment, Confirmatory, Multi-	14-Apr-2024	Conferences	https://ebmt2024.abstractserver.com/program/#/details/presentations/1304

			centered, Pivotal/ Registration, Global Trial, Superiority Trial	centered, Pharmacoeconomics, Pivotal/ Registration, Global Trial, Superiority Trial			
16-Apr-2024	Trial Result	Trial Results Updated			05-Apr-2024	Conferences	https://www.abstractsonline.com/pp8/#!/20272/presentation/10384
12-Mar-2024	Study Design/ Trial Description	Trial Description Updated			28-Feb-2024	Clinical Trial Registry	https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/study/44808
08-Mar-2024	Trial Date	Trial Actual End Date Added **"18 Mar 2021"**	N/A	18 Mar 2021	07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=53&B=55&C=Side-by-Side#StudyPageTop
08-Mar-2024	Primary/ Secondary outcomes	Primary Outcome Measures Updated			07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=53&B=55&C=Side-by-Side#StudyPageTop
08-Mar-2024	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=53&B=55&C=Side-by-Side#StudyPageTop
08-Mar-2024	Study Design/ Trial Description	Trial Description Updated			07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=53&B=55&C=Side-by-Side#StudyPageTop

08-Mar-2024	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=53&B=55&C=Side-by-Side#StudyPageTop
08-Mar-2024	Subjects	Inclusion Criteria Updated			07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=53&B=55&C=Side-by-Side#StudyPageTop
08-Mar-2024	Trial Result	Trial Results Updated			07-Mar-2024	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/show/results/NCT03391466
27-Feb-2024	Acronym/Secondary ID	Trial Secondary ID Updated	016278, 113165, 17-541, 1818GCCC, 19341, 2017-002261-22, 2017-0699, 2018-008, 2018-01359, 20729, EudraCT-2017-002261-22, IND-016278, KTE-C19-107, KTE-C19-107 (ZUMA-7),	016278, 113165, 17-541, 1818GCCC, 19341, 2017-002261-22, 2017-0699, 2018-008, 2018-01359, 20729, BASEC 2018-01359, EudraCT-2017-002261-22, IND-016278, KTE-C19-107, KTE-C19-	22-Feb-2024	Clinical Trial Registry	https://kofam.ch/en/snctp-portal/searching-for-a-clinical-trial/study/44808

			MOH_2018-08-07_002200, NCI-2018-00042, NCT03391466, OSU-17326, SNCTP000003107, TEC-C19-107, UMGCC1818 GCCC, XX-0051	107 (ZUMA-7), MOH_2018-08-07_002200, NCI-2018-00042, NCT03391466, OSU-17326, SNCTP000003107, TEC-C19-107, UMGCC1818 GCCC, XX-0051			
15-Feb-2024	Trial Result	Pooled Results Updated			06-Sep-2023	Conferences	https://clml-soho2023.elsevierdigitaledition.com/index.html
08-Jan-2024	Trial Result	Trial Results Updated			09-Dec-2023	Conferences	https://ashpublications.org/blood/article/142/Supplement%201/6899/500947/Statistical-Challenges-from-Trials-of-Potentially
28-Dec-2023	Study Design/ Trial Description	Trial Description Updated			09-Dec-2023	Conferences	https://ash.confex.com/ash/2023/webprogram/Paper173798.html
28-Dec-2023	Trial Result	Pooled Results Updated			09-Dec-2023	Clinical Trial Registry	https://ash.confex.com/ash/2023/webprogram/Paper173798.html
26-Dec-	Trial	Interim			21-Dec-	Company	https://www.gilea

2023	Result	Results Updated			2023	Press Release	d.com/news-and-press/press-room/press-releases/2023/12/us-fda-approves-label-update-for-kites-yescarta-car-tcell-therapy-to-include-overall-survival-data
26-Dec-2023	Study Design/ Trial Description	Trial Description Updated			21-Dec-2023	Company Press Release	https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/us-fda-approves-label-update-for-kites-yescarta-car-tcell-therapy-to-include-overall-survival-data
14-Dec-2023	Trial Result	Sub-group Analysis Updated			11-Dec-2023	Company Press Release	https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/analyses-of-kites-yescartacar-t-cell-therapy-support-curative-potential-in-patients-with-non-hodgkin-lymphomas
14-Dec-2023	Trial Result	Trial Conclusion Updated			11-Dec-2023	Company Press Release	https://www.gilead.com/news-and-press/press-room/press-releases/2023/12/analyses-of-kites-yescartacar-t-cell-therapy-support-curative-potential-in-patients-with-non-hodgkin-lymphomas
13-Dec-2023	Biomarkers	Biomarkers Updated	B and T Lymphocyte Associated; BCL2 Apoptosis Regulat	B and T Lymphocyte Associated; BCL2 Apoptosis Regulat	09-Dec-2023	Conferences	https://ash.confex.com/ash/2023/webprogram/Paper173873.html

			or; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1;	or; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1;			

			Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily membe	Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily membe			

			r 17	r 17; Tumor Burden			
13-Dec-2023	Biomarkers	Biomarkers Updated	B and T Lymphocyte Associated; BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2;	B and T Lymphocyte Associated; BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-C Motif Chemokine Receptor 7; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule;	09-Dec-2023	Conferences	https://ash.confex.com/ash/2023/webprogram/Paper173873.html

			Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor;	Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncoge			

			Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily member 17; Tumor Burden	ne, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily member 17; Tumor Burden			
13-Dec-2023	Biomarkers	Biomarkers Updated	B and T Lymphocyte Associated; BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-C Motif Chemokine Recept	B and T Lymphocyte Associated; BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-C Motif Chemokine Recept	09-Dec-2023	Conferences	https://ash.confex.com/ash/2023/webprogram/Paper173873.html

			or 7; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10; Interleukin 15;	or 7; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; CD45RA; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10;			

			Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily member 17; Tumor Burden	Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily member 17; Tumor Burden			
12-Dec-2023	Primary/ Secondary outcome	Secondary Outcome Measures Updated			09-Dec-2023	Conferences	https://ash.confex.com/ash/2023/webprogram/Paper173873.html

	s						
12-Dec-2023	Trial Result	Sub-group Analysis Updated			09-Dec-2023	Conferences	https://ash.confex.com/ash/2023/webprogram/Paper173873.html
24-Jul-2023	Study Design/ Trial Description	Trial Description Updated			18-Jul-2023	Company Press Release	https://www.prnewswire.com/news-releases/yikaida-car-t-cell-therapy-approved-as-a-second-line-therapy-for-new-indication-301880444.html
24-Jul-2023	Trial Result	Trial Conclusion Updated			18-Jul-2023	Company Press Release	https://www.prnewswire.com/news-releases/yikaida-car-t-cell-therapy-approved-as-a-second-line-therapy-for-new-indication-301880444.html
20-Jul-2023	Trial Result	Pooled Results Updated			13-Jun-2023	Conferences	https://onlinelibrary.wiley.com/doi/10.1002/hon.3164_234
19-Jul-2023	Trial Status	Trial Status Changed from **"Ongoing, not recruiting"** to **"Completed"**	Ongoing, not recruiting	Completed	17-Feb-2022	Journals	https://www.nejm.org/doi/full/10.1056/NEJMoa2116133
19-Jul-2023	Study Design/ Trial Description	Trial Description Updated			13-Jun-2023	Conferences	https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
19-Jul-2023	Trial Result	Trial Results Updated			13-Jun-2023	Conferences	https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
19-Jul-2023	Endpoint Status	Endpoint Status Updated to	N/A	Achieved	17-Feb-2022	Journals	https://www.nejm.org/doi/full/10.1056/NEJMoa2116133

		"Achieved "					
19-Jul-2023	Enrollment	Number of Subjects Analyzed Updated to **"359"**	N/A	359	13-Jun-2023	Conferences	https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
19-Jul-2023	Trial Result	Trial Conclusion Updated			13-Jun-2023	Conferences	https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
19-Jul-2023	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			13-Jun-2023	Conferences	https://onlinelibrary.wiley.com/doi/10.1002/hon.3163_22
07-Jul-2023	Primary/ Secondary outcomes	Primary Outcome Measures Updated			06-Jul-2023	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=52&B=53&C=Side-by-Side#StudyPageTop
07-Jul-2023	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			06-Jul-2023	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=52&B=53&C=Side-by-Side#StudyPageTop
03-Jul-2023	Trial Result	Pooled Results Updated			02-Jun-2023	Conferences	https://meetings.asco.org/abstracts-presentations/220315
23-Jun-2023	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			22-Jun-2023	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=51&B=52&C=Side-by-Side#Eligibility
23-Jun-2023	Study Design/ Trial Description	Trial Description Updated			22-Jun-2023	Clinical Trial Registry	https://classic.clinicaltrials.gov/ct2/history/NCT03391466?A=51&B=52&C=Side-by-Side#Eligibility
08-Jun-2023	Trial Result	Preliminary Results Updated			02-Jun-2023	Conferences	https://meetings.asco.org/abstracts-presentations/220

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08-Jun-2023	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			02-Jun-2023	Conferences	https://meetings.asco.org/abstracts-presentations/220014
08-Jun-2023	Trial Result	Trial Results Updated			05-Jun-2023	Company Press Release	https://www.gilead.com/news-and-press/press-room/press-releases/2023/6/kites-yescarta-car-t-cell-therapy-demonstrates-significantly-longer-overall-survival-versus-standard-of-care-as-initial-treatment-of-relapsedrefrac
08-Jun-2023	Study Design/ Trial Description	Trial Description Updated			05-Jun-2023	Journals	https://www.nejm.org/doi/full/10.1056/NEJMoa2301665
08-Jun-2023	Trial Result	Trial Results Updated			05-Jun-2023	Journals	https://www.nejm.org/doi/full/10.1056/NEJMoa2301665
03-May-2023	Trial Result	Trial Results Updated			23-Apr-2023	Conferences	https://ebmt2023.abstractserver.com/program/#/details/presentations/791
02-May-2023	Trial Result	Trial Results Updated			23-Feb-2023	Conferences	https://ebmt2023.abstractserver.com/program/#/details/presentations/790
02-May-2023	Study Design/ Trial Description	Trial Description Updated			23-Apr-2023	Conferences	https://ebmt2023.abstractserver.com/program/#/details/presentations/790
23-Mar-2023	Study Design/ Trial Description	Trial Description Updated			21-Mar-2023	Company Press Release	https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-

							demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract
23-Mar-2023	Study Design/ Trial Description	Trial Description Updated			21-Mar-2023	Company Press Release	https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract
23-Mar-2023	Trial Result	Trial Results Updated			21-Mar-2023	Company Press Release	https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract
23-Mar-2023	Study Design/ Trial Description	Trial Notes Updated			21-Mar-2023	Company Press Release	https://www.kitepharma.com/news/press-releases/2023/3/kites-yescarta-car-t-cell-therapy-demonstrates-a-statistically-significant-improvement-in-overall-survival-for-initial-treatment-of-relapsedrefract
23-Feb-2023	Trial Result	Trial Results Updated			15-Feb-2023	Conferences	https://astct-29-s2.elsevierdigitaledition.com/
22-Feb-2023	Trial Result	Trial Results Updated			15-Feb-2023	Conferences	https://astct-29-s2.elsevierdigitaledition.com/

06-Feb-2023	Trial Date	Trial Estimated End Date Changed from **"01 Jan 2023"** to **"25 Jan 2023"**	01 Jan 2023	25 Jan 2023	03-Feb-2023	Clinical Trial Registry	https://clinicaltrials.gov/ct2/history/NCT03391466?A=49&B=51&C=Side-by-Side#StudyPageTop
12-Jan-2023	Trial Result	Pooled Results Updated			10-Dec-2022	Conferences	https://ashpublications.org/blood/article/140/Supplement%201/4655/490968/Matching-Adjusted-Indirect-Comparison-MAIC-of?searchresult=1
29-Dec-2022	Trial Result	Trial Results Updated			10-Sep-2018	Regulatory Website	https://www.ema.europa.eu/en/documents/product-information/yescarta-epar-product-information_en.pdf
13-Dec-2022	Trial Result	Trial Results Updated			11-Dec-2022	Conferences	https://ash.confex.com/ash/2022/webprogram/Paper158303.html
13-Dec-2022	Trial Result	Trial Conclusion Updated					
13-Dec-2022	Trial Result	Post-hoc Results Updated			11-Dec-2022	Company Press Release	https://www.gilead.com/news-and-press/press-room/press-releases/2022/12/body-of-evidence-grows-from-zuma-7-study-supporting-initial-treatment-with-kites-yescarta-car-t-cell-therapy-for-patients-with-relapsed-or-refractor
13-Dec-2022	Trial Result	Trial Results Updated			10-Dec-2022	Conferences	https://ash.confex.com/ash/2022/webprogram/Paper158492.html
19-Oct-2022	Study Design/ Trial	Trial Description Updated			17-Oct-2022	Company Press Release	https://www.gilead.com/news-and-press/press-room/press-

	Description						releases/2022/10/kites-yescarta-first-car-t-cell-therapy-to-receive-european-marketing-authorization-for-use-in-second-line-diffuse-large-b-cell-lymphoma-and-high-gra
13-Jul-2022	Subjects	Trial Subjects Updated	Chronic Disease, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	Chronic Disease, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	11-Jun-2022	Conferences	https://library.ehaweb.org/eha/2022/eha2022-congress/357075/anna.sureda.clinical.and.patient-reported.outcomes.in.a.phase.3.study.of.html?f=menu%3D6%2Abrowseby%3D8%2Asortby%3D2%2Amedia%3D3%2Ace_id%3D2233%2Aot_id%3D26858%2Amarker%3D1751
13-Jul-2022	Subjects	Trial Subjects Updated	Chronic Disease, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	Chronic Disease, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	11-Jun-2022	Conferences	https://library.ehaweb.org/eha/2022/eha2022-congress/357075/anna.sureda.clinical.and.patient-reported.outcomes.in.a.phase.3.study.of.html?f=menu%3D6%2Abrowseby%3D8%2Asortby%3D2%2Amedia%3D3%2Ace_id%3D2233%2Aot_id%3D26858%2Amarker%3D1751
13-Jul-	Trial	Sub-group			11-Jun-	Conference	https://library.eh

2022	Result	Analysis Updated			2022	s	aweb.org/eha/2022/eha2022-congress/357075/anna.sureda.clinical.and.patient-reported.outcomes.in.a.phase.3.study.of.html?f=menu%3D6%2Abrowseby%3D8%2Asortby%3D2%2Amedia%3D3%2Ace_id%3D2233%2Aot_id%3D26858%2Amarker%3D1751
28-Jun-2022	Trial Result	Trial Results Updated			04-Jun-2022	Conferences	https://meetings.asco.org/abstracts-presentations/209948
24-Jun-2022	Subjects	Exclusion Criteria Updated			21-Jun-2022	Clinical Trial Registry	https://reec.aemps.es/reec/public/detail.html
24-Jun-2022	Subjects	Inclusion Criteria Updated			21-Jun-2022	Clinical Trial Registry	https://reec.aemps.es/reec/public/detail.html
20-Jun-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-	20-Jun-2022	Company Press Release	https://www.businesswire.com/news/home/20220604005006/en/Sub-analyses-of-Landmark-ZUMA-7-Trial-Reinforce-Yescarta%C2%AE-CAR-T-cell-Therapy-Superiority-Over-Standard-of-Care-SOC-as-Initial-Treatment-for-Patients-With-Relapsed-or-Refractory-Large-B-cell-Lymphoma-LBCL

			X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcription Factor	X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; MYC Proto-Oncogene, bHLH Transcription Factor			
20-Jun-	Biomark	Biomarker	BCL2	BCL2	20-Jun-	Journals	https://meetings.asco.org/abstract

2022	ers	s Updated	Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1;	Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesio	2022		s-presentations/210240

			Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; MYC Proto-Oncogene, bHLH Transcription Factor	n molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; MYC Proto-Oncogene, bHLH Transcription Factor			
20-Jun-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand	20-Jun-2022	Journals	https://meetings.asco.org/abstracts-presentations/210240

			10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; MYC Proto-Oncogene, bHLH Transcr	10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domain			

			iption Factor	s A1; MYC Proto-Oncogene, bHLH Transcription Factor			
20-Jun-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor	20-Jun-2022	Journals	https://meetings.asco.org/abstracts-presentations/210240

			2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor	2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; TNF receptor superfamily			

				member 17			
20-Jun-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4,	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4,	20-Jun-2022	Journals	https://meetings.asco.org/abstracts-presentations/210240

			Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; TNF receptor superfamily member 17	Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily			

				member 17			
20-Jun-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4,	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4,	20-Jun-2022	Journals	https://meetings.asco.org/abstracts-presentations/210240

			Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily	Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor; Protein Tyrosine Phosphatase Recept			

			member 17	or Type C; TNF receptor superfamily member 17			
20-Jun-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule; Colony stimulating factor 2;	B and T Lymphocyte Associated; BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; CD19 molecule;	20-Jun-2022	Journals	https://meetings.asco.org/abstracts-presentations/210240

			Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncogene, bHLH Transcription Factor;	Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interferon regulatory factor 8; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; L-Lactate Dehydrogenase; Membrane spanning 4-domains A1; MYC Proto-Oncoge			

			Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily member 17	ne, bHLH Transcription Factor; Protein Tyrosine Phosphatase Receptor Type C; TNF receptor superfamily member 17			
14-Jun-2022	Trial Result	Trial Results Updated			04-Jun-2022	Conferences	https://meetings.asco.org/abstracts-presentations/210240
14-Jun-2022	Trial Result	Trial Results Updated			04-Jun-2022	Company Press Release	https://www.businesswire.com/news/home/20220604005006/en/Sub-analyses-of-Landmark-ZUMA-7-Trial-Reinforce-Yescarta%C2%AE-CAR-T-cell-Therapy-Superiority-Over-Standard-of-Care-SOC-as-Initial-Treatment-for-Patients-With-Relapsed-or-Refractory-Large-B-cell-Lymphoma-LBCL
13-Jun-2022	Trial Result	Trial Results Updated			04-Jun-2022	Conferences	https://meetings.asco.org/abstracts-presentations/209923
24-May-2022	Trial Result	Preliminary Results Updated			16-May-2022	Conferences	https://www.cell.com/molecular-therapy-family/molecular-therapy/pdf/S1525-

							0016(22)00246-5.pdf
10-May-2022	Endpoint Classification	Endpoint Classification Updated	Efficacy,Quality of Life,Safety	Efficacy,Pharmacokinetics, Quality of Life,Safety			
09-May-2022	Trial Result	Trial Results Updated			26-Apr-2022	Conferences	https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/20530
04-May-2022	Trial Locations	Trial Locations Updated			29-Apr-2022	Clinical Trial Registry	https://clinicaltrials.gov/ct2/history/NCT03391466?A=47&B=49&C=Side-by-Side#StudyPageTop
02-May-2022	Subjects	Trial Subjects Updated	Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	Chronic Disease, Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	29-Apr-2022	Clinical Trial Registry	https://clinicaltrials.gov/ct2/history/NCT03391466?A=47&B=49&C=Side-by-Side#StudyPageTop
29-Apr-2022	Trial Result	Trial Results Updated			27-Apr-2022	Company Press Release	https://www.esmo.org/oncology-news/fda-approves-axicabtagene-ciloleucel-for-second-line-treatment-of-large-b-cell-lymphoma

27-Apr-2022	Trial Result	Trial Results Updated			26-Apr-2022	Conferences	https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19266
26-Apr-2022	Trial Result	Trial Results Updated			25-Apr-2022	Conferences	https://tandem.confex.com/tandem/2022/meetingapp.cgi/Paper/19351
21-Apr-2022	Biomarkers	Biomarkers Updated	N/A	Interleukin 6	11-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/12678
21-Apr-2022	Biomarkers	Biomarkers Updated	Interleukin 6	C-X-C Motif Chemokine Ligand 8; Interleukin 6	11-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/12678
21-Apr-2022	Biomarkers	Biomarkers Updated	C-X-C Motif Chemokine Ligand 8; Interleukin 6	C-X-C Motif Chemokine Ligand 8; Interleukin 27; Interleukin 6	11-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/12678
21-Apr-2022	Biomarkers	Biomarkers Updated	C-X-C Motif Chemokine Ligand 8; Interleukin 27; Interleukin 6	C-reactive protein; C-X-C Motif Chemokine Ligand 8; Interleukin 27; Interleukin 6	11-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/12678
21-Apr-2022	Biomarkers	Biomarkers Updated	C-reactive	C-c Motif	11-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/pres

			protein; C-X-C Motif Chemokine Ligand 8; Interleukin 27; Interleukin 6	Chemokine Ligand 4; C-reactive protein; C-X-C Motif Chemokine Ligand 8; Interleukin 27; Interleukin 6			entation/12678
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C Motif Chemokine Ligand 8; Interleukin 27; Interleukin 6	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C Motif Chemokine Ligand 8; Granzyme B; Interleukin 27; Interleukin 6	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146

			Motif Chemokine Ligand 8; Granzyme B; Interleukin 27; Interleukin 6	Motif Chemokine Ligand 8; Ferritins; Granzyme B; Interleukin 27; Interleukin 6			
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Interleukin 27; Interleukin 6	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Interleukin 10; Interleukin 27; Interleukin 6	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein;	C-c Motif Chemokine Ligand 4; C-reactive protein;	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146

			C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Interleukin 10; Interleukin 27; Interleukin 6	C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Interleukin 10; Interleukin 27; Interleukin 6			
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzy	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzy	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146

			me B; Interleukin 10; Interleukin 27; Interleukin 6	me B; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6			
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27;	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146

				Interleukin 6			
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6	10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146

21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncoge	25-Feb-2022	Clinical Trial Registry	https://clinicaltrials.gov/ct2/show/NCT03391466

				ne, bHLH Transcription Factor			
21-Apr-2022	Biomarkers	Biomarkers Updated	C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleu	BCL2 Apoptosis Regulator; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleu	25-Feb-2022	Clinical Trial Registry	https://clinicaltrials.gov/ct2/show/NCT03391466

			kin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcription Factor	kin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcription Factor			
21-Apr-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritin	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony	25-Feb-2022	Clinical Trial Registry	https://clinicaltrials.gov/ct2/show/NCT03391466

			s; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcription Factor	stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcription Factor			
21-Apr-2022	Biomarkers	Biomarkers Updated	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-	BCL2 Apoptosis Regulator; BCL6 Transcription Repressor; C-c Motif Chemokine Ligand 4; C-	25-Feb-2022	Clinical Trial Registry	https://clinicaltrials.gov/ct2/show/NCT03391466

			reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcription Factor	reactive protein; C-X-C motif chemokine ligand 10; C-X-C Motif Chemokine Ligand 8; Colony stimulating factor 2; Ferritins; Granzyme B; Herpesvirus 4, Human; Intercellular adhesion molecule 1; Interleukin 10; Interleukin 15; Interleukin 27; Interleukin 6; MYC Proto-Oncogene, bHLH Transcr			

				iption Factor			
20-Apr-2022	Primary/ Secondary outcomes	Secondary Outcome Measures Updated					
20-Apr-2022	Study Design/ Trial Description	Trial Description Updated					
20-Apr-2022	Study Design/ Trial Description	Trial Description Updated					
20-Apr-2022	Study Design/ Trial Description	Trial Notes Updated					
20-Apr-2022	Trial Result	Trial Results Updated			11-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/12678
20-Apr-2022	Subjects	Inclusion Criteria Updated					
19-Apr-2022	Trial Result	Trial Results Updated			10-Apr-2022	Conferences	https://www.abstractsonline.com/pp8/#!/10517/presentation/20146
29-Mar-2022	Trial Result	Trial Results Updated			23-Mar-2022	Conferences	https://ebmt2022.abstractserver.com/program/#/details/presentations/855
25-Mar-2022	Trial Result	Trial Results Updated			22-Mar-2022	Conferences	https://ebmt2022.abstractserver.com/program/#/details/presentations/819
25-Mar-2022	Study Design/ Trial	Trial Description Updated					

	Description						
25-Mar-2022	Subjects	Trial Subjects Updated	Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status	Eastern Cooperative Oncology Group (ECOG or WHO or Zubrod) Performance Status			
24-Mar-2022	Trial Result	Trial Results Updated			19-Mar-2022	Conferences	https://ebmt2022.abstractserver.com/program/#/details/presentations/1024
23-Mar-2022	Trial Result	Trial Results Updated			19-Mar-2022	Conferences	https://ebmt2022.abstractserver.com/program/#/details/presentations/805
07-Jan-2022	Trial Result	Trial Results Updated			12-Dec-2021	Conferences	https://ash.confex.com/ash/2021/webprogram/Paper147598.html
06-Jan-2022	Trial Result	Trial Results Updated			11-Dec-2021	Journals	https://www.nejm.org/doi/full/10.1056/NEJMoa2116133
13-Dec-2021	Primary/ Secondary outcomes	Primary Outcome Measures Updated			12-Dec-2021	Conferences	https://ash.confex.com/ash/2021/webprogram/Paper148039.html
13-Dec-2021	Primary/ Secondary outcomes	Secondary Outcome Measures Updated			12-Dec-2021	Conferences	https://ash.confex.com/ash/2021/webprogram/Paper148039.html
13-Dec-2021	Study Design/	Trial Descriptio			12-Dec-2021	Conferences	https://ash.confex.com/ash/2021/

	Trial Description	n Updated					webprogram/Paper148039.html
13-Dec-2021	Subjects	Inclusion Criteria Updated			12-Dec-2021	Conferences	https://ash.confex.com/ash/2021/webprogram/Paper148039.html
13-Dec-2021	Trial Result	Trial Results Updated			12-Dec-2021	Conferences	https://ash.confex.com/ash/2021/webprogram/Paper148039.html
19-Oct-2021	Trial Date	Trial Actual Start Date Changed from **"14 Dec 2017"** to **"25 Jan 2018"**	14 Dec 2017	25 Jan 2018	14-Oct-2021	Clinical Trial Registry	https://clinicaltrials.gov/ct2/history/NCT03391466?A=46&B=47&C=Side-by-Side#StudyPageTop
11-Oct-2021	Trial Date	Trial Estimated End Date Changed from **"15 Jan 2022"** to **"01 Jan 2023"**	15 Jan 2022	01 Jan 2023	08-Oct-2021	Clinical Trial Registry	https://clinicaltrials.gov/ct2/history/NCT03391466?A=44&B=46&C=Side-by-Side#StudyPageTop
06-Aug-2021	Trial Result	Trial Results Updated			04-Aug-2021	Company Press Release	https://www.kumc.edu/news-listing-page/zuma-7.html
30-Jun-2021	Study Design/ Trial Description	Trial Description Updated					https://www.gilead.com/news-and-press/press-room/press-releases/2021/6/kite-announces-yescarta-car-tcell-therapy-improved-eventfree-survival-by-60-over-chemotherapy-plus-stem-cell-transplant-in-secondline-relapsed-or
30-Jun-2021	Trial Result	Trial Results					https://www.gilead.com/news-and-press/press-

		Updated					room/press-releases/2021/6/kite-announces-yescarta-car-tcell-therapy-improved-eventfree-survival-by-60-over-chemotherapy-plus-stem-cell-transplant-in-secondline-relapsed-or
30-Jun-2021	Trial Result	Trial Conclusion Updated					
12-May-2021	Study Design/ Trial Description	Trial Description Updated					https://clinicaltrials.gov/ct2/show/NCT03391466
12-May-2021	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/9fc6ee8f-b63c-451b-a8a8-9136bdcfc54c
12-May-2021	Subjects	Trial Subjects Updated					https://clinicaltrials.gov/ct2/show/NCT03391466
12-May-2021	Sponsor/ Collaborator/CRO	Trial Sponsors Updated					
16-Feb-2021	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/079f6f7e-62bb-44c9-88e9-64b48d9be9f5
08-Feb-2021	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/da2a6be6-1c7a-4769-aa73-8f00408c91a3
30-Oct-2020	Study Design/	Trial Notes					http://investors.gilead.com/static-files/7db4987f-

	Trial Description	Updated					930d-4b18-877e-0c75d5e34c0d
08-Oct-2020	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					https://clinicaltrials.gov/ct2/history/NCT03391466?A=38&B=44&C=Side-by-Side#StudyPageTop
27-Aug-2020	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/cd67608e-573e-4a6a-8131-aee5b9e2453e
31-Jul-2020	Trial Locations	Trial Locations Updated					https://trials.cancervic.org.au/details.aspx?ID=vctl_nct03391466
31-Jul-2020	Trial Contacts	Trial Contacts Updated					
29-Jul-2020	Sponsor/ Collaborator/CRO	Trial Sponsors Updated					https://clinicaltrials.gov/ct2/show/NCT03391466
29-Jul-2020	Acronym/Secondary ID	Trial Secondary ID Updated					
15-Jun-2020	Acronym/Secondary ID	Trial Secondary ID Updated					http://www.abedia.com/wiley/record_detail.php?ID=2978
06-May-2020	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/af4599eb-4fb8-4cf7-96a1-38caf477e9b4
15-Apr-2020	Trial Locations	Trial Locations Updated					
08-Apr-2020	Trial Location	Trial Locations					https://clinicaltrials.gov/ct2/history

	s	Updated					/NCT03391466?A=42&B=43&C=Side-by-Side#StudyPageTop
02-Mar-2020	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/36dc002c-bce8-4242-b087-f4e388d6b606
02-Dec-2019	Sponsor/ Collaborator/CRO	Trial Sponsors Updated					
07-Nov-2019	Trial Locations	Trial Locations Updated					
05-Nov-2019	Study Design/ Trial Description	Trial Description Updated					https://clinicaltrials.gov/ct2/history/NCT03391466?A=36&B=38&C=Side-by-Side#StudyPageTop
05-Nov-2019	Trial Result	Trial Conclusion Updated					https://clinicaltrials.gov/ct2/history/NCT03391466?A=36&B=38&C=Side-by-Side#StudyPageTop
05-Nov-2019	Trial Status	Trial Status Changed from **"Ongoing, recruiting"** to **"Ongoing, not recruiting"**	Ongoing, recruiting	Ongoing, not recruiting			https://clinicaltrials.gov/ct2/history/NCT03391466?A=36&B=38&C=Side-by-Side#StudyPageTop
05-Nov-2019	Subjects	Trial Subjects Updated					
05-Nov-2019	Enrollment	Number of Subjects	N/A	359			

		Enrolled Changed from "N/A" to "359"					
02-Aug-2019	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/575b248b-e0bc-4220-9386-e3f555cacc79
02-Aug-2019	Trial Locations	Trial Locations Updated					
31-Jul-2019	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					
31-Jul-2019	Trial Locations	Trial Locations Updated					
26-Jun-2019	Sponsor/ Collaborator/CRO	Trial Sponsors Updated					
18-May-2019	Drug/Intervention	Secondary Intervention Updated					
18-May-2019	Indications	Trial Indications Updated					
18-May-2019	Primary/ Secondary outcomes	Primary Outcome Measure Updated					
18-May-2019	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					

18-May-2019	Drug/Intervention	Secondary Intervention Updated					
15-May-2019	Trial Locations	Trial Locations Updated					
10-May-2019	Acronym/Secondary ID	Trial Secondary ID Updated					https://healthcare.utah.edu/huntsmancancerinstitute/clinical-trials/trial.php?id=20505&no=113165
10-May-2019	Acronym/Secondary ID	Trial Secondary ID Updated					https://www.mdanderson.org/patients-family/diagnosis-treatment/clinical-trials/clinical-trials-index/clinical-trials-detail.ID2017-0699.html
10-May-2019	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/ead8235f-ab4e-4d0e-b354-453b3d6820a2
10-May-2019	Subjects	Inclusion Criteria Updated					
10-May-2019	Trial Contacts	Trial Contacts Updated					
08-May-2019	Trial Locations	Trial Locations Updated					
08-May-2019	Trial Locations	Trial Locations Updated					
15-Apr-2019	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					https://ebmt2019.abstractmgmt.com/uploads/ebmt2019/30-presentation.pdf (Slide 20)

04-Apr-2019	Acronym/Secondary ID	Trial Secondary ID Updated					
13-Mar-2019	Trial Locations	Trial Locations Updated					
12-Mar-2019	Trial Locations	Trial Locations Updated					
12-Mar-2019	Trial Contacts	Trial Contacts Updated					
12-Mar-2019	Acronym/Secondary ID	Trial Secondary ID Updated					
12-Mar-2019	Trial Contacts	Trial Contacts Updated					
28-Feb-2019	Trial Contacts	Trial Contacts Updated					
14-Feb-2019	Trial Locations	Trial Locations Updated					
08-Feb-2019	Trial Locations	Trial Locations Updated					
05-Feb-2019	Study Design/ Trial Description	Trial Notes Updated					http://investors.gilead.com/static-files/d37c8017-5ae2-40d1-b8e3-371604c33341
01-Feb-2019	Trial Locations	Trial Locations Updated					
31-Jan-2019	Trial Locations	Trial Locations Updated					

31-Jan-2019	Trial Contacts	Trial Contacts Updated					
31-Jan-2019	Trial Contacts	Trial Contacts Updated					
18-Jan-2019	Trial Locations	Trial Locations Updated					
14-Jan-2019	Trial Locations	Trial Locations Updated					
02-Jan-2019	Acronym/Secondary ID	Trial Secondary ID Updated					
02-Jan-2019	Trial Contacts	Trial Contacts Updated					
02-Jan-2019	Trial Contacts	Trial Contacts Updated					
26-Dec-2018	Trial Locations	Trial Locations Updated					
26-Dec-2018	Trial Locations	Trial Locations Updated					
20-Dec-2018	Primary/ Secondary outcomes	Primary Outcome Measure Updated					
20-Dec-2018	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					
20-Dec-2018	Study Design/	Trial Descriptio					

	Trial Description	n Updated					
20-Dec-2018	Subjects	Exclusion Criteria Updated					
20-Dec-2018	Subjects	Inclusion Criteria Updated					
18-Dec-2018	Trial Locations	Trial Locations Updated					
14-Dec-2018	Trial Locations	Trial Locations Updated					
12-Dec-2018	Primary/ Secondary outcomes	Primary Outcome Measure Updated					
12-Dec-2018	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					
12-Dec-2018	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					
12-Dec-2018	Subjects	Exclusion Criteria Updated					
12-Dec-2018	Subjects	Inclusion Criteria Updated					
16-Nov-2018	Trial Contacts	Trial Contacts Updated					
20-Sep-	Trial	Trial					

2018	Locations	Locations Updated					
20-Sep-2018	Trial Contacts	Trial Contacts Updated					
20-Sep-2018	Acronym/Secondary ID	Trial Acronym Updated					
18-Sep-2018	Trial Locations	Trial Locations Updated					
18-Sep-2018	Trial Contacts	Trial Contacts Updated					
18-Sep-2018	Acronym/Secondary ID	Trial Secondary ID Updated					
22-Aug-2018	Trial Locations	Trial Locations Updated					
10-Aug-2018	Trial Locations	Trial Locations Updated					
10-Aug-2018	Trial Contacts	Trial Contacts Updated					
03-Aug-2018	Trial Locations	Trial Locations Updated					
03-Aug-2018	Trial Contacts	Trial Contacts Updated					
30-Jul-2018	Trial Locations	Trial Locations Updated					
30-Jul-2018	Trial Contacts	Trial Contacts Updated					

27-Jul-2018	Study Design/ Trial Description	Trial Notes Updated					phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9NDA4OTU1fENoaWxkSUQ9LTF8VHlwZT0z&t=1&cb=636680582523475446
26-Jul-2018	Trial Locations	Trial Locations Updated					
26-Jul-2018	Trial Contacts	Trial Contacts Updated					
26-Jul-2018	Subjects	Trial Subjects Updated					
24-Jul-2018	Primary/ Secondary outcomes	Primary Outcome Measure Updated					
24-Jul-2018	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					
24-Jul-2018	Study Design/ Trial Description	Trial Description Updated					
24-Jul-2018	Trial Contacts	Trial Contacts Updated					
11-Jul-2018	Trial Locations	Trial Locations Updated					
11-Jul-2018	Trial Locations	Trial Locations Updated					
11-Jul-2018	Trial Contacts	Trial Contacts					

		Updated					
11-Jul-2018	Trial Contacts	Trial Contacts Updated					
03-Jul-2018	Trial Locations	Trial Locations Updated					
03-Jul-2018	Trial Contacts	Trial Contacts Updated					
03-Jul-2018	Trial Contacts	Trial Contacts Updated					
27-Jun-2018	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					http://abstracts.asco.org/214/AbstView_214_211185.html
27-Jun-2018	Primary/ Secondary outcomes	Primary Outcome Measure Updated					
25-Jun-2018	Trial Locations	Trial Locations Updated					
25-Jun-2018	Trial Contacts	Trial Contacts Updated					
21-Jun-2018	Trial Locations	Trial Locations Updated					
21-Jun-2018	Trial Contacts	Trial Contacts Updated					
19-Jun-2018	Trial Contacts	Trial Contacts Updated					
14-Jun-2018	Trial Location	Trial Locations					

	s	Updated					
14-Jun-2018	Trial Contacts	Trial Contacts Updated					
13-Jun-2018	Acronym/Secondary ID	Trial Secondary ID Updated					
13-Jun-2018	Drug/Intervention	Secondary Intervention Updated					
13-Jun-2018	Study Design/ Trial Description	Trial Description Updated					
13-Jun-2018	Trial Contacts	Trial Contacts Updated					
13-Jun-2018	Acronym/Secondary ID	Trial Secondary ID Updated					
13-Jun-2018	Trial Date	Trial Estimated Start Date Changed from **"01 Dec 2017"** to **"19 Mar 2018"**	01 Dec 2017	19 Mar 2018			
05-Jun-2018	Trial Locations	Trial Locations Updated					
05-Jun-2018	Trial Contacts	Trial Contacts Updated					
25-May-2018	Trial Locations	Trial Locations Updated					

22-May-2018	Trial Locations	Trial Locations Updated					
22-May-2018	Trial Contacts	Trial Contacts Updated					
16-May-2018	Trial Locations	Trial Locations Updated					
16-May-2018	Trial Contacts	Trial Contacts Updated					
07-May-2018	Trial Locations	Trial Locations Updated					
07-May-2018	Trial Contacts	Trial Contacts Updated					
09-Apr-2018	Trial Locations	Trial Locations Updated					
09-Apr-2018	Trial Locations	Trial Locations Updated					
09-Apr-2018	Trial Contacts	Trial Contacts Updated					
05-Apr-2018	Acronym/Secondary ID	Trial Secondary ID Updated					
05-Apr-2018	Trial Contacts	Trial Contacts Updated					
04-Apr-2018	Study Design/ Trial Description	Trial Description Updated					
04-Apr-	Trial	Trial					

2018	Contacts	Contacts Updated					
27-Mar-2018	Trial Locations	Trial Locations Updated					
27-Mar-2018	Trial Contacts	Trial Contacts Updated					
22-Mar-2018	Trial Phase	Trial Phase Changed from **"Phase II/III"** to **"Phase III"**	Phase II/III	Phase III			
22-Mar-2018	Acronym/Secondary ID	Trial Secondary ID Updated					
22-Mar-2018	Primary/Secondary outcomes	Primary Outcome Measure Updated					
22-Mar-2018	Primary/Secondary outcomes	Secondary Outcome Measure Updated					
22-Mar-2018	Study Design/Trial Description	Trial Description Updated					
22-Mar-2018	Subjects	Exclusion Criteria Updated					
22-Mar-2018	Subjects	Inclusion Criteria Updated					

15-Mar-2018	Trial Locations	Trial Locations Updated					
15-Mar-2018	Trial Contacts	Trial Contacts Updated					
12-Mar-2018	Primary/ Secondary outcomes	Secondary Outcome Measure Updated					
12-Mar-2018	Trial Contacts	Trial Contacts Updated					
11-Jan-2018	Trial Locations	Trial Locations Updated					
11-Jan-2018	Trial Contacts	Trial Contacts Updated					
08-Jan-2018	Trial Date	Trial Actual Start Date Updated					
08-Jan-2018	Trial Date	Trial Estimated End Date Updated					
08-Jan-2018	Trial Status	Trial Status Changed from **"Planned"** to **"Ongoing, recruiting"**	Planned	Ongoing, recruiting			
08-Jan-2018	Acronym/Secondary ID	Trial Secondary ID Updated					

08-Jan-2018	Drug/Intervention	Secondary Intervention Updated					
08-Jan-2018	Primary/Secondary outcomes	Primary Outcome Measure Updated					
08-Jan-2018	Primary/Secondary outcomes	Secondary Outcome Measure Updated					
08-Jan-2018	Study Design/ Trial Description	Trial Description Updated					
08-Jan-2018	Subjects	Exclusion Criteria Updated					
08-Jan-2018	Subjects	Inclusion Criteria Updated					
08-Jan-2018	Subjects	Trial Subjects Updated					
08-Jan-2018	Study Design/ Trial Description	Study Design Updated					
08-Jan-2018	Enrollment	Number of Subjects Planned Changed from "N/A" to "350"	N/A	350			
08-Jan-2018	Trial Result	Trial Conclusio					

		n Updated					
08-Jan-2018	Trial Contacts	Trial Contacts Updated					
08-Jan-2018	Trial Contacts	Trial Contacts Updated					
27-Jun-2017	Study Design/ Trial Description	Trial Notes Updated					http://wsw.com/webcast/jeff105/kite/?lobby=true&day=2 (Slides 22,24)
20-Jun-2017	Study Design/ Trial Description	Trial Notes Updated					http://files.shareholder.com/downloads/AMDA-2V2XOY/3931323970x0x945757/29F0F521-5728-4871-AB18-3F8519098BB7/Kite_Corporate_Presentation_-_June_2017.pdf
20-Apr-2017	Study Design/ Trial Description	Trial Notes Updated					http://files.shareholder.com/downloads/AMDA-2V2XOY/4314053637x0x931905/DFBB279C-1240-420C-B5B6-FC7A5B4EFC01/KITE_Corporate_Presentation_-_April_2017.pdf
03-Apr-2017	Study Design/ Trial Description	Trial Notes Updated					http://wsw.com/webcast/cowen38/kite/ (Slides 08,09,25)
10-Mar-2017	Study Design/ Trial Description	Trial Notes Updated					http://files.shareholder.com/downloads/AMDA-2V2XOY/3905183343x0x931905/DFBB279C-1240-420C-B5B6-FC7A5B4EFC01/KITE_Corporate_Presentation_-_March_2017.pdf
06-Mar-	Study	Trial					http://files.shareholder.com/downlo

2017	Design/ Trial Description	Notes Updated					ads/AMDA-2V2XOY/3931323970x0xS1510580%2D17%2D3/1510580/filing.pdf
19-Jan-2017	Miscellaneous	Trial notes updated					http://files.shareholder.com/downloads/AMDA-2V2XOY/3690731638x0x923850/0DDC9807-9379-4C1F-9FBB-C0293699C109/Kite_Pharma_-_JP_Morgan_Presentation_.pdf
23-Dec-2016	Subjects	Subject Types Updated					files.shareholder.com/downloads/AMDA-2V2XOY/3473479470x0x915808/BBCD802C-ECE9-4848-B1B6-8D34D532E12C/KitePharma_Investor_Day_Presentation_-_10.18.16.pdf
21-Oct-2016	Miscellaneous,Trial Date	Acronym, Estimated start date, Description					http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=994338
06-Sep-2016	Miscellaneous	Trial notes updated, Supplementation source added					http://wsw.com/webcast/canaccord23/kite/?lobby=true&day=1; http://files.shareholder.com/downloads/AMDA-2V2XOY/2041976751x0x881656/E054796E-7D95-4263-B319-482BB8DCAA23/Corporate_Presentation_-_June_2016.pdf
16-Apr-2015	Trial Date	Trial start date changed;					http://ir.kitepharma.com/releasedetail.cfm?ReleaseID=903451

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Last Reviewed on 19 Apr 2024