

ClinicalTrials.gov: cell therapy | Last update posted in the last 7 days

|   | NCT Number  | Title  | Other Names  | Status             | Conditions  | Interventions   | Characteristics  | Population  | Sponsor/Collaborators   | Dates  |
|---|-------------|--|--|--------------------|---|---|--|---|---|--|
| 1 | NCT04115345 | <a href="#">A Study of a Renal Autologous Cell Therapy (REACT®) in Patients With Chronic Kidney Disease (CKD) From Congenital Anomalies of the Kidney and Urinary Tract (CAKUT).</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids:<br>REGEN-004            | Recruiting         | <ul style="list-style-type: none"><li>Chronic Kidney Disease</li><li>Congenital Anomalies of Kidney and Urinary Tract</li></ul> | Biological: Renal Autologous Cell Therapy (REACT®)<br>Autologous selected renal cells (SRC) | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Intervention Model Description: Open-label<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: Assess change in eGFR and observe incidence of renal-specific procedure and/or product related adverse events (AEs) through 24 months following two Renal Autologous Cell Therapy (REACT) injections [Safety]. [ Time Frame: 12 months following last REACT injection ]<br>The primary objective is to assess the safety and optimal delivery of Renal Autologous Cell Therapy (REACT) injected at one site in a recipient kidney as measured by procedure- and/or product related adverse events (AEs) through 12 months post-treatment.<br><br>Secondary Outcome Measures: Number of subjects with renal-specific adverse events over a 24-month period following injection of Renal Autologous Cell Therapy (REACT). [ Time Frame: 24 months following last REACT injection ]<br>The number of subjects with renal-specific adverse events over a 24-month period following injection of Renal Autologous Cell Therapy (REACT) will be observed utilizing renal-specific laboratory assessments.The secondary objective will compare the results of laboratory tests from baseline through 12 months following REACT injection, followed by an additional observational period of 18 months for a total of 24 months of observation. Each subject's baseline rate of CKD disease progression serves as his/her own "control" to monitor for changes in renal insufficiency over time. | Actual Enrollment:<br><br>Estimated Enrollment: 15<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years to 65 Years (Adult, Older Adult)<br><br>Sex: All     | Study Sponsors: <i>Same as current</i><br><br>Collaborators: CTI Clinical Trial and Consulting Services | Study Start: August 13, 2019<br><br>Primary Completion: March 31, 2023 (Final data collection date for primary outcome measure)<br><br>Study Completion: May 30, 2023<br><br>First Posted: October 4, 2019<br><br>Results First Posted:<br><br>Last Update Posted: September 16, 2022        |
| 2 | NCT05237986 | <a href="#">Cognitive Aftereffects of Neurotoxicity in Children and Young Adults With Relapsed/Refractory Hematologic Malignancies Who Receive CAR T-cell Therapy</a><br><br>Study Documents:                | Title Acronym:<br><br>Other Ids:<br>10000631<br>000631-C | Not yet recruiting | <ul style="list-style-type: none"><li>Lymphoma</li><li>Leukemia</li></ul>   | Not Provided  | Study Type: Observational<br><br>Phase:<br><br>Study Design: Observational Model: Cohort<br>Time Perspective: Prospective<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i>  | Actual Enrollment:<br><br>Estimated Enrollment: 60<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 5 Years and older (Child, Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <i>Same as current</i><br><br>Collaborators: Not Provided                               | Study Start: September 22, 2022<br><br>Primary Completion: April 30, 2024 (Final data collection date for primary outcome measure)<br><br>Study Completion: April 30, 2025<br><br>First Posted: February 14, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 19, 2022 |

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| 3 | NCT03240328 | <a href="#">The Effect of Chimeric Antigen Receptor (CAR)-T Cell Therapy on the Reconstitution of HIV-specific Immune Function</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids:<br>20170407V3 | Recruiting | HIV/AIDS   | Biological: CAR-T cells<br>HIV-1 specific chimeric antigen receptor cells  | <div>Study Type: Interventional</div> <div>Phase: Phase 1</div> <div>Study Design: Allocation: N/A<br/>Intervention Model: Single Group Assignment<br/>Intervention Model Description:<br/>No control.<br/>Masking: None (Open Label)<br/>Primary Purpose: Treatment</div> <div>Primary Outcome Measures: Incidence of Treatment-Emergent Adverse Events of CAR-T cell therapy [ Time Frame: 6 Months ]<br/>The adverse events of VC-CAR-T cell therapy on HIV-infected patients during the clinical trial</div> <div>Secondary Outcome Measures: The HIV reservoir [ Time Frame: 6 Months ]<br/>To assay the HIV loads in the peripheral blood Mono-nuclear cells and plasma</div> | <div>Actual Enrollment:</div> <div>Estimated Enrollment: 40</div> <div>Original Estimated Enrollment:<br/><i>Same as current</i></div> <div>Age: 18 Years to 60 Years (Adult)</div> <div>Sex: All</div>            | <div>Study Sponsors:<br/><i>Same as current</i></div> <div>Collaborators:<br/>Sun Yat-sen University</div> | <div>Study Start:<br/>October 4, 2017</div> <div>Primary Completion:<br/>December 31, 2023 (Final data collection date for primary outcome measure)</div> <div>Study Completion:<br/>December 31, 2030</div> <div>First Posted:<br/>August 7, 2017</div> <div>Results First Posted:</div> <div>Last Update Posted:<br/>September 14, 2022</div> |
| 4 | NCT04637763 | <a href="#">CRISPR-Edited Allogeneic Anti-CD19 CAR-T Cell Therapy for Relapsed/Refractory B Cell Non-Hodgkin Lymphoma</a><br><br>Study Documents:          | Title Acronym:<br><br>Other Ids:<br>CB10A      | Recruiting | <ul style="list-style-type: none"><li>Lymphoma, Non-Hodgkin</li><li>Relapsed Non-Hodgkin Lymphoma</li><li>Refractory B-Cell Non-Hodgkin Lymphoma</li><li>Non-Hodgkin Lymphoma</li><li>Lymphoma</li><li>B Cell Lymphoma</li><li>B Cell Non-Hodgkin's Lymphoma</li></ul> | <ul style="list-style-type: none"><li>Genetic: CB-010<br/>CB-010 is a CRISPR-edited allogeneic CAR-T cell therapy targeting CD19.</li><li>Drug: Cyclophosphamide<br/>Chemotherapy for lymphodepletion</li><li>Drug: Fludarabine<br/>Chemotherapy for lymphodepletion</li></ul> | <div>Study Type: Interventional</div> <div>Phase: Phase 1</div> <div>Study Design: Allocation: Non-Randomized<br/>Intervention Model: Sequential Assignment<br/>Intervention Model Description:<br/>The CB10A clinical study consists of 3 + 3 design with three dose levels.<br/>Masking: None (Open Label)<br/>Primary Purpose: Treatment</div> <div>Primary Outcome Measures: <i>Same as current</i></div> <div>Secondary Outcome Measures: Not Provided</div>   | <div>Actual Enrollment:</div> <div>Estimated Enrollment: 50</div> <div>Original Estimated Enrollment:<br/><i>Same as current</i></div> <div>Age: 18 Years and older (Adult, Older Adult)</div> <div>Sex: All</div> | <div>Study Sponsors:<br/><i>Same as current</i></div> <div>Collaborators:<br/>Not Provided</div>           | <div>Study Start:<br/>May 26, 2021</div> <div>Primary Completion:<br/>August 2025 (Final data collection date for primary outcome measure)</div> <div>Study Completion:<br/>September 2025</div> <div>First Posted:<br/>November 20, 2020</div> <div>Results First Posted:</div> <div>Last Update Posted:<br/>September 19, 2022</div>          |

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|---|-------------|--|---|--------------------|--|--|--|--|---|---|
| 5 | NCT05541549 | <a href="#">A Phase 2 Study Evaluating JCPyV-specific T Cell Therapy for PML</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: 20210001 | Not yet recruiting | Progressive Multifocal Leukoencephalopathy | Biological: CE-VST01-JC<br>CE-VST01-JC at a dose of $1 \times 10^8$ cells administered as an intravenous (IV) infusion every 28 days for 4 total infusions | <div>Study Type: Interventional</div> <div>Phase: Phase 2</div> <div>Study Design: Allocation: Randomized<br/>Intervention Model: Parallel Assignment<br/>Intervention Model Description: randomized, double- blinded, Phase 2 trial in patients with PML due to JCPyV.<br/>Masking: Triple (Participant, Care Provider, Investigator)<br/>Primary Purpose: Treatment</div> <div>Primary Outcome Measures: To evaluate the effect of CE-VST01-JC on time to disease progression, as measured by mRS (modified Rankin Score) [ Time Frame: 1 year ]<br/>Time to progression as measured by mRS. A progression event is defined as an increase of 2 points on mRS attributable to disease progression* that is durable (not reversed over two consecutive measurements, at least 14 days apart), or an increase to mRS of 5 or 6 (severe disability or death, respectively).</div> <div>Secondary Outcome Measures: Not Provided</div> | <div>Actual Enrollment:</div> <div>Estimated Enrollment: 60</div> <div>Original Estimated Enrollment: <i>Same as current</i></div> <div>Age: 18 Years and older (Adult, Older Adult)</div> <div>Sex: All</div> | <div>Study Sponsors: <a href="#">Same as current</a></div> <div>Collaborators: Not Provided</div> | <div>Study Start: February 2023</div> <div>Primary Completion: March 2024 (Final data collection date for primary outcome measure)</div> <div>Study Completion: April 2025</div> <div>First Posted: September 15, 2022</div> <div>Results First Posted:</div> <div>Last Update Posted: September 16, 2022</div> |

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| 6 | NCT03696030 | <a href="#">HER2-CAR T Cells in Treating Patients With Recurrent Brain or Leptomeningeal Metastases</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: 17237 NCI-2018-01270 ( Registry Identifier: CTRP (Clinical Trial Reporting Program) ) 17237 ( Other Identifier: City of Hope Medical Center ) | Recruiting | <ul style="list-style-type: none"><li>• Malignant Neoplasm</li><li>• Metastatic Malignant Neoplasm in the Brain</li><li>• Metastatic Malignant Neoplasm in the Leptomeninges</li><li>• Breast Cancer</li><li>• HER2-positive Breast Cancer</li></ul> | Biological: Chimeric Antigen Receptor T-Cell Therapy<br>Given HER2-CAR T cells via intraventricular administration<br><br>Other Names: <ul style="list-style-type: none"><li>• CAR T Infusion</li><li>• CAR T Therapy</li><li>• CAR T-cell therapy</li><li>• Chimeric Antigen Receptor T-cell Infusion</li></ul> | <div>Study Type: Interventional</div> <div>Phase: Phase 1</div> <div>Study Design: Allocation: Non-Randomized<br/>Intervention Model: Single Group Assignment<br/>Masking: None (Open Label)<br/>Primary Purpose: Treatment</div> <div>Primary Outcome Measures:<ul style="list-style-type: none"><li>• Incidence of dose limiting toxicities (DLTs) [ Time Frame: 21 days post T cell infusion ]<br/><br/>Rate and associated 90% Clopper and Pearson binomial confidence limits (90% CI) will be estimated for participants experiencing DLTs at the recommended phase 2 dose schedule.</li><li>• Number of participants with treatment related adverse events as assessed by CTCAE v5.0. [ Time Frame: Up to 15 years ]<br/><br/>Tables will be created to summarize all toxicities and side effects by dose, time post treatment, organ, severity and arm.</li></ul></div> <div>Secondary Outcome Measures:<ul style="list-style-type: none"><li>• HER2-CAR T cells in cerebrospinal fluid (CSF) and peripheral blood [ Time Frame: Measured over time from baseline through 1 year, the number of measurements is determined by whether or not the participant has progressed (progressed: baseline, 1, 3, 6,and 12 months, not progressed: baseline, 1, 3,6,8,10 and 12 months) ]<br/><br/>Statistical and graphical methods will be used to describe the data.</li><li>• Endogenous B cells in cerebrospinal fluid (CSF) and peripheral blood [ Time Frame: Measured over time from baseline through 1 year, the number of measurements is determined by whether or not the participant has progressed (progressed: baseline, 1, 3, 6,and 12 months, not progressed: baseline, 1, 3,6,8,10 and 12 months) ]<br/><br/>Statistical and graphical methods will be used to describe the data.</li><li>• T cells in cerebrospinal fluid (CSF) and peripheral blood [ Time Frame: progressed: baseline, 1, 3, 6, and 12 months, not progressed: baseline, 1, 3, 6, 8,10 and 12 months) ]<br/><br/>Statistical and graphical methods will be used to describe the data.</li><li>• Myeloid cells in cerebrospinal fluid (CSF) and peripheral blood [ Time Frame: Measured over time from baseline through 1 year, the number of measurements is determined by whether or not the participant has progressed (progressed: baseline, 1, 3, 6,and 12 months, not progressed: baseline, 1, 3,6,8,10 and 12 months) ]<br/><br/>Statistical and graphical methods will be used to describe the data.</li><li>• Host immune subsets (e.g. T cell inhibitory/exhaustion markers, activation markers, and effector memory T cells) in cerebrospinal fluid (CSF) and peripheral blood. [ Time Frame: Measured over time from baseline through 1 year, the number of measurements is determined by whether or not the participant has progressed (progressed: baseline, 1, 3, 6,and 12 months, not progressed: baseline, 1, 3,6,8,10 and 12 months) ]<br/><br/>Statistical and graphical methods will be used to describe the data.</li></ul></div> | <div>Actual Enrollment:</div> <div>Estimated Enrollment: 39</div> <div>Original Estimated Enrollment: 21</div> <div>Age: 18 Years to 75 Years (Adult, Older Adult)</div> <div>Sex: All</div> | <div>Study Sponsors: <a href="#">Same as current</a></div> <div>Collaborators:<ul style="list-style-type: none"><li>• National Cancer Institute (NCI)</li><li>• California Institute for Regenerative Medicine (CIRM)</li></ul></div> | <div>Study Start: August 31, 2018</div> <div>Primary Completion: August 31, 2023 (Final data collection date for primary outcome measure)</div> <div>Study Completion: August 31, 2023</div> <div>First Posted: October 4, 2018</div> <div>Results First Posted:</div> <div>Last Update Posted: September 16, 2022</div> |

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| 7 | NCT04007029 | <a href="#">Modified Immune Cells (CD19/CD20 CAR-T Cells) in Treating Patients With Recurrent or Refractory B-Cell Lymphoma or Chronic Lymphocytic Leukemia</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: 18-001989<br>NCI-2019-03190 ( Registry Identifier: CTRP (Clinical Trial Reporting Program) )<br>18-001989 ( Other Identifier: UCLA / Jonsson Comprehensive Cancer Center ) | Recruiting | <ul style="list-style-type: none"><li>CD19 Positive</li><li>CD20 Positive</li><li>Recurrent Chronic Lymphocytic Leukemia</li><li>Recurrent Diffuse Large B-Cell Lymphoma</li><li>Recurrent Follicular Lymphoma</li><li>Recurrent Mantle Cell Lymphoma</li><li>Recurrent Primary Mediastinal (Thymic) Large B-Cell Cell Lymphoma</li><li>Recurrent Small Lymphocytic Lymphoma</li><li>Refractory Chronic Lymphocytic Leukemia</li><li>Refractory Diffuse Large B-Cell Lymphoma</li><li>Refractory Follicular Lymphoma</li><li>Refractory Mantle Cell Lymphoma</li><li>Refractory Primary Mediastinal (Thymic) Large B-Cell Cell Lymphoma</li></ul> | <ul style="list-style-type: none"><li>Biological: Chimeric Antigen Receptor T-Cell Therapy<br/><br/>Given Autologous anti-CD19/anti-CD20 CAR-expressing naive/memory T cells IV<br/><br/>Other Names:<ul style="list-style-type: none"><li>CAR T Infusion</li><li>CAR T Therapy</li><li>CAR T-cell therapy</li><li>Chimeric Antigen Receptor T-cell Infusion</li></ul></li><li>Drug: Cyclophosphamide<br/><br/>Given IV<br/><br/>Other Names:<ul style="list-style-type: none"><li>(-)-Cyclophosphamide</li><li>2H-1,3,2-Oxazaphosphorine, 2-[bis(2-chloroethyl)amino]tetrahydro-, 2-oxide, monohydrate</li><li>Carloxan</li><li>Ciclofosfamida</li><li>Ciclofosfamide</li><li>Cicloxal</li><li>Clafen</li><li>Claphene</li><li>CP (cyclophosphamide) monohydrate</li><li>CTX (cytoxan)</li><li>CYCLO-cell</li><li>Cycloblastin</li><li>Cycloblastine</li><li>Cyclophospham</li><li>Cyclophosphamid monohydrate</li><li>Cyclophosphamidum</li><li>Cyclophosphan</li><li>Cyclophosphane</li><li>Cyclophosphanum</li><li>Cyclostin</li><li>Cyclostine</li><li>Cytophosphan</li><li>Cytophosphane</li><li>Cytoxan</li><li>Fosfaseron</li><li>Genoxal</li><li>Genuxal</li><li>Ledoxina</li><li>Mitoxan</li><li>Neosar</li><li>Revimmune</li><li>Syklofosfamid</li><li>WR- 138719</li></ul></li><li>Drug: Fludarabine Phosphate<br/><br/>Given IV<br/><br/>Other Names:<ul style="list-style-type: none"><li>2-F-ara-AMP fludarabine: 2-Fluoroadenine 9-beta-D-Arabinofuranoside 5'-Monophosphate</li><li>9H-Purin-6-amine, 2-fluoro-9-(5-O-phosphono-.beta.-D-arabinofuranosyl)-</li><li>Beneflur</li><li>Fludara</li><li>SH T 586</li></ul></li><li>Biological: Tocilizumab<br/><br/>Given IV<br/><br/>Other Names:<ul style="list-style-type: none"><li>Actemra</li><li>Immunoglobulin G1, Anti-(Human Interleukin 6 Receptor) (Human-Mouse Monoclonal MRA Heavy Chain), Disulfide with Human-Mouse Monoclonal MRA Kappa-Chain, Dimer</li><li>MRA (myeloma receptor antibody)</li><li>R-1569</li><li>RoActemra</li></ul></li></ul> | <p>Study Type: Interventional</p> <hr/> <p>Phase: Phase 1</p> <hr/> <p>Study Design: Allocation: N/A<br/>Intervention Model: Single Group Assignment<br/>Masking: None (Open Label)<br/>Primary Purpose: Treatment</p> <hr/> <p>Primary Outcome Measures: <i>Same as current</i></p> <hr/> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none"><li>Clinical response [ Time Frame: Up to 15 years ]<br/><br/>Descriptive statistics including simple summary measures and plots appropriate for longitudinal data will be used.</li><li>Duration of remission [ Time Frame: Time from complete remission (CR)/partial remission (PR) measurement criteria are first met until the first date that recurrent or progressive disease is objectively documented, or until death, assessed up to 15 years ]<br/><br/>Descriptive statistics including simple summary measures and plots appropriate for longitudinal data will be used. Will also be summarized descriptively (mean, standard deviation, median, first and third quartiles, minimum, maximum). Figures showing the Kaplan-Meier estimates will also be presented.</li><li>Objective response rate (ORR) [ Time Frame: Up to 15 years ]<br/><br/>Descriptive statistics including simple summary measures and plots appropriate for longitudinal data will be used. ORR and the individual rate for CR and PR will be summarized with the frequency count and the percentage of subjects in each category, along with a 2-sided 95% exact confidence interval.</li><li>Progression-free survival [ Time Frame: From time of study entry to documentation of objective disease progression or death due to any cause assessed up to 15 years ]<br/><br/>Descriptive statistics including simple summary measures and plots appropriate for longitudinal data will be used. Will also be summarized descriptively (mean, standard deviation, median, first and third quartiles, minimum, maximum). Figures showing the Kaplan-Meier estimates will also be presented.</li><li>Overall survival [ Time Frame: From date of enrollment until death, assessed up to 15 years ]<br/><br/>Descriptive statistics including simple summary measures and plots appropriate for longitudinal data will be used. Will be summarized with figures using the Kaplan-Meier method. The Kaplan-Meier estimates for the 1-year OS rates and the 2-sided 95% confidence interval of the rates using the Greenwood's formula will be reported. Will also be summarized descriptively (mean, standard deviation, median, first and third quartiles, minimum, maximum).</li><li>Chimeric antigen receptor (CAR) T-cell (T) 19/20 bispecific transgenic T-cell persistence [ Time Frame: Up to 5 years post-infusion ]<br/><br/>Descriptive statistics of T-cell counts over time, including simple summary measures and plots appropriate for longitudinal data will be used.</li><li>Frequency of T cell phenotypic markers on CART19/20 cells using flow cytometry [ Time Frame: Up to 5 years post-infusion ]<br/><br/>The frequency of CART19/20 cell properties will be assessed using flow cytometry to indicate the % and/or total number of CART19/20 cells expressing critical</li></ul> | <p>Actual Enrollment:</p> <hr/> <p>Estimated Enrollment: 24</p> <hr/> <p>Original Estimated Enrollment: <i>Same as current</i></p> <hr/> <p>Age: 18 Years to 70 Years (Adult, Older Adult)</p> <hr/> <p>Sex: All</p> | <p>Study Sponsors: <i>Same as current</i></p> <hr/> <p>Collaborators: Parker Institute for Cancer Immunotherapy</p> | <p>Study Start: October 4, 2019</p> <hr/> <p>Primary Completion: August 1, 2023 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: August 1, 2024</p> <hr/> <p>First Posted: July 5, 2019</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 13, 2022</p> |



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| 8 | NCT05050006 | <a href="#">ITIL-168 in Advanced Melanoma</a><br><br>Study Documents:   | Title Acronym:<br><br>Other Ids: ITIL-168-101<br>2020-003862-37<br>( EudraCT Number ) | Recruiting | Advanced Cutaneous Melanoma   | Biological: ITIL-168<br>ITIL-168 is a cell therapy product derived from a patient's own TILs. A tumor sample is removed from each patient to make a personalized ITIL-168 product. Once ITIL-168 has been made, the patient is treated with 5 days of lymphodepleting chemotherapy including cyclophosphamide and fludarabine, followed by a single infusion of ITIL-168, and up to 8 doses of IL-2. | Study Type: Interventional<br><br>Phase: Phase 2<br><br>Study Design: Allocation: Non-Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description:<br>All enrolled participants are assigned to be treated with a single dose of ITIL-168<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i> | Actual Enrollment:<br><br>Estimated Enrollment: 130<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years and older<br>(Adult, Older Adult)<br><br>Sex: All  | Study Sponsors: <i>Same as current</i><br><br>Collaborators: Not Provided | Study Start: October 7, 2021<br><br>Primary Completion: March 2024<br>(Final data collection date for primary outcome measure)<br><br>Study Completion: August 2028<br><br>First Posted: September 20, 2021<br><br>Results First Posted:<br><br>Last Update Posted: September 16, 2022        |
| 9 | NCT04684459 | <a href="#">Dual-targeting HER2 and PD-L1 CAR-T for Cancers With Pleural or Peritoneal Metastasis</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: MCART-002  | Recruiting | <ul style="list-style-type: none"><li>Peritoneal Carcinoma Metastatic</li><li>Pleural Effusion, Malignant</li></ul> | Biological: Dual-targeting HER2 and PD-L1 CAR-T cells<br>serosal cavity infusion   | Study Type: Interventional<br><br>Phase: Early Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i>  | Actual Enrollment:<br><br>Estimated Enrollment: 18<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years to 70 Years<br>(Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <i>Same as current</i><br><br>Collaborators: Not Provided | Study Start: March 12, 2021<br><br>Primary Completion: January 1, 2023<br>(Final data collection date for primary outcome measure)<br><br>Study Completion: January 1, 2024<br><br>First Posted: December 24, 2020<br><br>Results First Posted:<br><br>Last Update Posted: September 13, 2022 |

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| 10 | NCT05540964 | <a href="#">An Antiretroviral Treatment Interruption(ATI) Study to Evaluate the Impact of AGT103-T to Suppress Human Immunodeficiency Virus Replication in the Absence of Antiretroviral Therapy</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: AGT-HC-169 | Enrolling by invitation | HIV  | Other: Antiretroviral Therapy Interruption(ATI)<br>Study participant that were previously infused with autologous genetically modified cell product will be taken off ART and followed closely by monitoring HIV rebound.   | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Intervention Model Description:<br>All study participant that consent to the study will be withdrawn from their Antiretroviral Therapy(ART) and monitored closely by clinic visit and laboratory testing of blood sample collected during each visit.<br>Masking: None (Open Label)<br>Primary Purpose: Diagnostic<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i> | Actual Enrollment:<br><br>Estimated Enrollment: 7<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years and older (Adult, Older Adult)<br><br>Sex: All    | Study Sponsors: <i>Same as current</i><br><br>Collaborators: Not Provided | Study Start: July 19, 2022<br><br>Primary Completion: July 19, 2025 (Final data collection date for primary outcome measure)<br><br>Study Completion: July 19, 2025<br><br>First Posted: September 15, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 15, 2022       |
| 11 | NCT05477927 | <a href="#">Dual-targeting VEGFR1 and PD-L1 CAR-T for Cancers Patients With Pleural or Peritoneal Metastases</a><br><br>Study Documents:   | Title Acronym:<br><br>Other Ids: MCART-006  | Recruiting              | <ul style="list-style-type: none"><li>• Malignant Peritoneal Effusion</li><li>• Malignant Ascites</li><li>• Serous Cavity Metastases</li></ul> | Biological: Dual-targeting VEGFR1 and PD-L1 CAR-T cells<br>In the dose escalation part, the dose levels will be escalated following a traditional escalation scheme for 3+3 design.<br>In the dose expansion part, patients will be assigned to different groups based on pleural or peritoneal metastases condition. | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i>   | Actual Enrollment:<br><br>Estimated Enrollment: 58<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years to 65 Years (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <i>Same as current</i><br><br>Collaborators: Not Provided | Study Start: October 30, 2022<br><br>Primary Completion: December 31, 2024 (Final data collection date for primary outcome measure)<br><br>Study Completion: December 31, 2024<br><br>First Posted: July 28, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 19, 2022 |

|    | NCT Number  | Title   | Other Names                                       | Status     | Conditions  | Interventions  | Characteristics  | Population  | Sponsor/Collaborators  | Dates   |
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| 12 | NCT04310592 | <a href="#">Natural Killer Cell (CYNK-001) Infusions in Adults With AML</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: CYNK-001-AML-001 | Recruiting | <ul style="list-style-type: none"><li>Leukemia</li><li>Leukemia, Myeloid</li><li>Leukemia, Myeloid, Acute</li><li>Neoplasms by Histologic Type</li><li>Neoplasms</li><li>Immunosuppressive Agents</li><li>Immunologic Factors</li><li>Physiological Effects of Drugs</li><li>Alkylating Agents</li><li>Antimetabolites, Antineoplastic</li><li>Antiviral Agents</li><li>Analgesics, Non-narcotic</li><li>Anti-infective Agents</li><li>Analgesics</li><li>Peripheral Nervous System Agents</li><li>Hematologic Diseases</li><li>Hematologic Neoplasms</li><li>Leukemia in Remission</li><li>Relapsed Adult AML</li><li>Refractory AML</li></ul> | Biological: CYNK-001<br>CYNK-001 is an allogeneic off the shelf cell therapy enriched for CD56+/CD3- NK cells expanded from human placental CD34+ cells. | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: Non-Randomized<br>Intervention Model: Parallel Assignment<br>Intervention Model Description:<br>Experimental: Minimal Residual Disease (MRD) positive AML patients; Cyclophosphamide + Fludarabine + CYNK-001. On Days 0, 7, and 14, (and 21 in certain arms) CYNK-001 at 3 varying dose levels.<br><br>Experimental: Relapsed/Refractory AML patients; Cyclophosphamide + Fludarabine + CYNK-001. On Days 0, 7, and 14, (and 21 at certain dose levels) CYNK-001 at 3 varying dose levels.<br><br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <ul style="list-style-type: none"><li>Number of Participants who experience a Dose-limiting Toxicity (DLT) [ Time Frame: Day +28 ]<br/><br/>    The number of participants who experience a DLT will be measured.</li><li>Determine the Maximum Tolerated Dose (MTD) or Maximum Planned Dose (MPD) of CYNK-001 [ Time Frame: up to 28 days ]<br/><br/>    The maximum dose safely administered for the treatment of patients with AML.</li><li>Frequency and Severity of Adverse Events (AEs) [ Time Frame: up to 12 months ]<br/><br/>    Frequency and severity of Adverse Events will be evaluated.</li></ul><br>Secondary Outcome Measures: <ul style="list-style-type: none"><li>Number of Participants who experience Minimal Residual Disease (MRD) Response [ Time Frame: up to 12 months ]<br/><br/>    The number of participants who convert from MRD positive to MRD negative.</li><li>Time to MRD Response [ Time Frame: up to 12 months ]<br/><br/>    The time it takes to convert from MRD positive to MRD negative.</li><li>Duration of MRD Response [ Time Frame: up to 12 months ]<br/><br/>    The measure of how long participants remain MRD negative.</li><li>Progression-free Survival (PFS) [ Time Frame: up to 12 months ]<br/><br/>    Date of first CYNK-001 infusion to date of disease progression.</li><li>Time to Progression (TTP) [ Time Frame: up to 12 months ]<br/><br/>    Date of first CYNK-001 infusion to date of disease progression.</li><li>Duration of Morphologic Complete Remission (CR) [ Time Frame: up to 12 months ]<br/><br/>    Duration from first Morphologic CR observation to time of disease progression.</li><li>Overall Survival (OS) [ Time Frame: up to 12 months ]<br/><br/>    Date of first CYNK-001 infusion to date of death.</li></ul> | Actual Enrollment:<br><br>Estimated Enrollment: 94<br><br>Original Estimated Enrollment: 22<br><br>Age: 18 Years to 80 Years (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided | Study Start: March 12, 2020<br><br>Primary Completion: June 3, 2024 (Final data collection date for primary outcome measure)<br><br>Study Completion: December 3, 2024<br><br>First Posted: March 17, 2020<br><br>Results First Posted:<br><br>Last Update Posted: September 14, 2022 |



|    | NCT Number  | Title   | Other Names   | Status     | Conditions   | Interventions   | Characteristics   | Population  | Sponsor/Collaborators   | Dates  |
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| 13 | NCT00001405 | <a href="#">Recruitment and Apheresis Collection of Peripheral Blood Hematopoietic Stem Cells, Mononuclear Cells and Granulocytes</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids:<br>940073<br>94-I-0073 | Recruiting | <ul style="list-style-type: none"><li>• Granuloma</li><li>• Granulomatous Disease, Chronic</li><li>• Leukocyte Disease</li><li>• Genetic Disease, X-Linked</li><li>• Genetic Disease, Inborn</li></ul> | Not Provided  | Study Type: Observational<br><br>Phase:<br><br>Study Design: Observational Model: Cohort<br>Time Perspective: Other<br><br>Primary Outcome Measures: Not Provided<br><br>Secondary Outcome Measures: Not Provided   | Actual Enrollment:<br><br>Estimated Enrollment: 850<br><br>Original Estimated Enrollment:<br><br>Age: 18 Years to 70 Years (Adult, Older Adult)<br><br>Sex: All                       | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided  | Study Start: February 27, 1994<br><br>Primary Completion: Not Provided<br><br>Study Completion: Not Provided<br><br>First Posted: November 4, 1999<br><br>Results First Posted:<br><br>Last Update Posted: September 19, 2022  |
| 14 | NCT05068674 | <a href="#">Human Embryonic Stem Cell-Derived Cardiomyocyte Therapy for Chronic Ischemic Left Ventricular Dysfunction</a><br><br>Study Documents:             | Title Acronym:<br><br>Other Ids:<br>60978               | Recruiting | Chronic Ischemic Left Ventricular Dysfunction  | <ul style="list-style-type: none"><li>• Drug: Human Embryonic Stem Cell-Derived Cardiomyocyte 50M cells<br/>50 million (M) cells delivered in a dose of 5M cells per injection over 10 injections.<br/>Other Name: Human ESC-CMs</li><li>• Drug: Human Embryonic Stem Cell-Derived Cardiomyocyte 150 cells<br/>150M cells delivered in a dose of 15M cells per injection over 10 injections<br/>Other Name: Human ESC-CMs</li><li>• Drug: Human Embryonic Stem Cell-Derived Cardiomyocyte 300M cells<br/>300M cells delivered in a dose of 30M per injection over 10 injections<br/>Other Name: Human ESC-CMs</li></ul> | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: Randomized<br>Intervention Model: Sequential Assignment<br>Intervention Model Description:<br>Phase I will be a standard 3+3 dose-escalation study to evaluate 3 doses of allogeneic hESC-CMs<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: Not Provided | Actual Enrollment:<br><br>Estimated Enrollment: 18<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 21 Years to 80 Years (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: California Institute for Regenerative Medicine (CIRM) | Study Start: March 22, 2022<br><br>Primary Completion: October 2025 (Final data collection date for primary outcome measure)<br><br>Study Completion: October 2025<br><br>First Posted: October 6, 2021<br><br>Results First Posted:<br><br>Last Update Posted: September 19, 2022 |

|    | NCT Number  | Title  | Other Names                                     | Status             | Conditions                             | Interventions   | Characteristics  | Population   | Sponsor/Collaborators  | Dates   |
|----|-------------|--|---|--------------------|--|---|--|--|--|---|
| 15 | NCT05539768 | <a href="#">Study on the Safety and Efficacy of Autogenous Tumor Infiltrates Lymphocytes for the Treatment of Advanced Solid Tumor</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: HS-IT101-ST001 | Not yet recruiting | Advanced Solid Tumor                   | Biological: HS-IT101<br>Adoptive transfer of 1x10^9-6x10^10 autologous TIL to patients i.v. in 30-60 minutes. | Study Type: Interventional<br><br>Phase: Early Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i> | Actual Enrollment:<br><br>Estimated Enrollment: 8<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years to 75 Years (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Qingdao Sino-Cell Biomedicine Co.,Ltd. | Study Start: October 8, 2022<br><br>Primary Completion: December 31, 2023 (Final data collection date for primary outcome measure)<br><br>Study Completion: March 31, 2027<br><br>First Posted: September 14, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 14, 2022 |
| 16 | NCT05544526 | <a href="#">CAR T Cells to Target GD2 for DMG</a><br><br>Study Documents:  | Title Acronym:<br><br>Other Ids: UCL/150853     | Not yet recruiting | Diffuse Midline Glioma, H3 K27M-Mutant | Biological: GD2 CAR T cells<br>Infusion with: GD2 CAR T-cells   | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i>       | Actual Enrollment:<br><br>Estimated Enrollment: 12<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: up to 16 Years (Child)<br><br>Sex: All                   | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided                           | Study Start: December 2022<br><br>Primary Completion: December 2025 (Final data collection date for primary outcome measure)<br><br>Study Completion: December 2039<br><br>First Posted: September 16, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 16, 2022        |

|    | NCT Number  | Title  | Other Names   | Status     | Conditions   | Interventions   | Characteristics   | Population  | Sponsor/Collaborators   | Dates   |
|----|-------------|--|---|------------|--|---|---|---|---|---|
| 17 | NCT04088864 | <a href="#">CD22-CAR T Cells in Children and Young Adults With B Cell Malignancies</a><br><br>Study Documents:                   | Title Acronym:<br><br>Other Ids: IRB-50878<br>CCT6003 ( Other Identifier: OnCore )<br>IRB-50878 ( Other Identifier: Stanford IRB )<br>NCI-2019-07285 ( Other Identifier: NCI Trial Identifier ) | Suspended  | <ul style="list-style-type: none"><li>B Cell Lymphoma</li><li>Acute Lymphoblastic Leukemia, Pediatric</li><li>Lymphoma</li></ul> | <ul style="list-style-type: none"><li>Drug: Fludarabine<br/>Fludarabine is a purine antagonist antimetabolite</li><li>Drug: Cyclophosphamide<br/>Cyclophosphamide is a nitrogen mustard derivative alkylating agent</li><li>Drug: Autologous CD22 CAR T<br/>Autologous T cells transduced with lentiviral vector (m971BBZ) Chimeric Antigen Receptor (CD22 CAR)</li></ul> | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: Non-Randomized<br>Intervention Model: Parallel Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i> | Actual Enrollment:<br><br>Estimated Enrollment: 52<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 1 Year to 30 Years (Child, Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided  | Study Start: January 10, 2020<br><br>Primary Completion: August 2025 (Final data collection date for primary outcome measure)<br><br>Study Completion: August 2035<br><br>First Posted: September 13, 2019<br><br>Results First Posted:<br><br>Last Update Posted: September 13, 2022 |
| 18 | NCT00012545 | <a href="#">Collection and Storage of Umbilical Cord Stem Cells for Treatment of Sickle Cell Disease</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: 010122<br>01-H-0122  | Recruiting | <ul style="list-style-type: none"><li>Sickle Cell Disease</li><li>Sickle Cell Trait</li></ul>                                    | Not Provided  | Study Type: Observational<br><br>Phase:<br><br>Study Design: Observational Model: Case-Only<br>Time Perspective: Cross-Sectional<br><br>Primary Outcome Measures: Not Provided<br><br>Secondary Outcome Measures: Not Provided  | Actual Enrollment:<br><br>Estimated Enrollment: 352<br><br>Original Estimated Enrollment:<br><br>Age: 18 Years to 45 Years (Adult)<br><br>Sex: All                            | Study Sponsors: <a href="#">National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)</a><br><br>Collaborators: Not Provided | Study Start: November 1, 2001<br><br>Primary Completion: Not Provided<br><br>Study Completion: Not Provided<br><br>First Posted: March 12, 2001<br><br>Results First Posted:<br><br>Last Update Posted: September 13, 2022  |

|    | NCT Number  | Title   | Other Names  | Status     | Conditions   | Interventions   | Characteristics  | Population   | Sponsor/Collaborators  | Dates   |
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| 19 | NCT05472558 | <a href="#">Clinical Study of Cord Blood-derived CAR-NK Cells Targeting CD19 in the Treatment of Refractory/Relapsed B-cell NHL</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: 2022-0496           | Recruiting | B-cell Non Hodgkin Lymphoma  | Biological: anti-CD19 CAR-NK lentiviral vector-transduced cord blood-derived NK cells to express anti-CD19 CAR<br>Other Name: CB CAR-NK019  | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i>   | Actual Enrollment:<br><br>Estimated Enrollment: 48<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years to 75 Years (Adult, Older Adult)<br><br>Sex: All  | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided | Study Start: September 10, 2022<br><br>Primary Completion: September 10, 2023 (Final data collection date for primary outcome measure)<br><br>Study Completion: September 10, 2025<br><br>First Posted: July 25, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 13, 2022    |
| 20 | NCT04102436 | <a href="#">Non-Viral TCR Gene Therapy</a><br><br>Study Documents:  | Title Acronym:<br><br>Other Ids: 190143<br>19-C-0143 | Recruiting | <ul style="list-style-type: none"><li>Endocrine/ Neuroendocrine</li><li>Non-Small Cell Lung Cancer</li><li>Breast Cancer</li><li>Gastrointestinal/Genitourinary Cancers</li><li>Ovarian Cancer</li></ul> | <ul style="list-style-type: none"><li>Drug: Fludarabine<br/>Days -7 to -3: Fludarabine 25 mg/m2/day IVPB daily over 30 minutes for 5 days.</li><li>Drug: Cyclophosphamide<br/>Days -7 and -6: Cyclophosphamide 60 mg/kg/day x 2 days IV in 250 mL D5W infused simultaneously with mesna 15 mg/kg/day over 1 hour x 2 days.</li><li>Drug: Aldesleukin<br/>Aldesleukin 720,000 IU/kg or 72,000 IU/kg (based on total body weight) IV over 15 minutes approximately every 8 hours beginning within 24 hours of cell infusion and continuing for up to 4 days (maximum 10 doses).</li><li>Biological: Sleeping Beauty Transposed PBL<br/>Day 0: Cells are to be infused at a dose not to exceed 1.5e11 in 400 mL intravenously on the Patient Care Unit over 20-30 minutes or as clinically determined by an investigator for patient safety (between 2-4 days after the last dose of fludarabine).</li></ul> | Study Type: Interventional<br><br>Phase: Phase 2<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <ul style="list-style-type: none"><li>Phenotypic and functional characteristics of PBL [ Time Frame: 2-4 years post cell infusion ]<br/><br/>Patient PBL will be obtained from whole blood and then evaluated for function and phenotype</li><li>Safety and tolerance [ Time Frame: 6 weeks (+/- 2 weeks) following administration of the cell product ]<br/><br/>Using standard CTCAE 5.0</li></ul> | Actual Enrollment:<br><br>Estimated Enrollment: 210<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years to 70 Years (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided | Study Start: September 22, 2022<br><br>Primary Completion: December 31, 2028 (Final data collection date for primary outcome measure)<br><br>Study Completion: December 31, 2029<br><br>First Posted: September 25, 2019<br><br>Results First Posted:<br><br>Last Update Posted: September 19, 2022 |

|    | NCT Number  | Title   | Other Names  | Status     | Conditions       | Interventions   | Characteristics | Population | Sponsor/Collaborators | Dates |
|----|-------------|---|--|------------|------------------|---|-----------------|------------|-----------------------|-------|
| 21 | NCT03654040 | <div><div><a href="#">Liver Transplantation With Tregs at UCSF</a></div><div>Study Documents:</div></div> | <div>Title Acronym:</div> <div>Other Ids: DAIT ITN074ST <a href="#">UM1AI109565 ( U.S. NIH Grant/Contract )</a> NIAID CRMS ID#: 38481 ( Other Identifier: DAIT NIAID )</div> | Recruiting | Liver Transplant | <div><div><div>• Biological: arTreg</div><div>Eligible participants will receive a single dose of Treg product (arTreg). The target dose is at least 90 x 10^6 total cells.</div><div>Method of receipt: peripheral intravenous (IV) infusion, administered over 20 to 30 minutes.</div><div>Other Names:<div><div>◦ donor alloantigen-reactive regulatory T cells</div><div>◦ CD4+CD25+CD127[lo] Treg cells</div></div></div></div><div><div>• Procedure: leukapheresis</div><div>Leukapheresis will be the method employed to recover peripheral blood mononuclear cells (PBMCs) from the allograft recipient. The recipient will undergo the procedure prior to initiating the cyclophosphamide conditioning regimen.</div><div>Procedure on Day -3 (-1 day) prior to Treg product (arTreg) IV infusion.</div><div>Other Name: apheresis</div></div><div><div>• Drug: cyclophosphamide</div><div>40 mg/kg administered intravenously (IV) following leukapheresis and between 1 to 3 days prior to Treg product (arTreg) infusion, per institutional standard of care.</div><div>Other Names:<div><div>◦ Cytosan®</div><div>◦ CTX</div></div></div><div><div>• Drug: mesna</div><div>Mesna is administered:<div><div>◦ Intravenously to inhibit hemorrhagic cystitis induced by cyclophosphamide, and</div><div>◦ In conjunction with the cyclophosphamide, per institutional practice with CTX.</div></div></div><div>Other Name: Mesnex®</div></div><div><div>• Drug: everolimus</div><div>EVR is approved for prophylaxis of allograft rejection in adults receiving a liver transplant. Per protocol: Post transplantation, subject will initially receive standard IS with tacrolimus (TAC).plus a mycophenolate product and/or steroids.Subsequently, evaluation for eligibility to be converted to EVR-based IS regimen will occur and, when applicable, proceed. Once the optimal EVR trough level is achieved,TAC dose will be reduced. When target EVR and TAC levels are maintained over two consecutive measurements, ALT liver function test (LFT) is 50 U/L, GGT LFT is the upper limit of normal or 1.5 times the baseline GGT, subject will be considered successfully converted to EVR-based IS regimen. EVR doses will be administered/monitored/adjusted over time.</div><div>Other Names:<div><div>◦ EVR</div><div>◦ Afinitor®</div><div>◦ Zortress®</div></div></div></div></div><div><div>Study Type: Interventional</div><div>Phase: Phase 1<br/>Phase 2</div><div>Study Design: Allocation: N/A<br/>Intervention Model: Single Group Assignment<br/>Masking: None (Open Label)<br/>Primary Purpose: Treatment</div><div>Primary Outcome Measures:<div><div>• Number of Adverse Events (AEs) Attributed to the Investigational Product, arTreg [ Time Frame: From arTreg infusion through completion of study participation (Up to 4.5 years) ]</div><div>The number of AEs attributed to the investigational product, arTreg. AEs will be attributed to arTreg when the AE is reported with possible or related attribution to arTreg.</div><div>• Severity of Adverse Events (AEs) Attributed to the Investigational Product, arTreg [ Time Frame: From arTreg infusion through completion of study participation (Up to 4.5 years) ]</div><div>Assessment of the intensity of AEs attributed to the investigational product, arTreg. AEs will be attributed to arTreg when the AE is reported with possible or related attribution to arTreg. Grading according to the NCI Common Terminology Criteria for Adverse Events [NCI-CTCAE version 5.0].</div><div>• Number of Adverse Events (AEs) Attributed to the Investigational Product's Supportive Regimen (Leukapheresis, Cyclophosphamide and Mesna) [ Time Frame: From 3 days prior to arTreg infusion through completion of study participation (Up to 4.5 years) ]</div><div>The number of AEs attributed to the investigational product's supportive regimen (leukapheresis, cyclophosphamide, and mesna). AEs will be attributed to the supportive regimen when the AE is reported with possible or related attribution to leukapheresis, cyclophosphamide, or mesna.</div><div>• Severity of Adverse Events (AEs) Attributed to the Investigational Product's Supportive Regimen (Leukapheresis, Cyclophosphamide and Mesna) [ Time Frame: From 3 days prior to arTreg infusion through completion of study participation (Up to 4.5 years) ]</div><div>Assessment of the intensity of AEs attributed to the investigational product's supportive regimen (e.g., leukapheresis, cyclophosphamide, and mesna). AEs will be attributed to the supportive regimen when the AE is reported with possible or related attribution to leukapheresis, cyclophosphamide, or mesna. Assessment of the intensity of AEs will be graded according to the NCI Common Terminology Criteria for Adverse Events [NCI-CTCAE version 5.0].</div><div>• Number of Operationally Tolerant Participants [ Time Frame: 52 weeks (±4 weeks) after the last dose of immunosuppression ]</div><div>Operational tolerance is defined as:<div><div>◦ Discontinuation of immunosuppression for 52 weeks,</div><div>◦ Alanine aminotransferase (ALT) and gamma-glutamyl transpeptidase (GGT) 50 U/L, and</div><div>◦ A liver biopsy at 52 weeks (±4 weeks) after the last dose of immunosuppression that meets the criteria noted per protocol.</div></div><div><div>■ Liver histology will be assessed by central pathology.</div></div></div></div><div>Actual Enrollment:</div><div>Estimated Enrollment: 9</div><div>Original Estimated Enrollment: <i>Same as current</i></div><div>Age: 18 Years to 70 Years (Adult, Older Adult)</div><div>Sex: All</div></div><div><div>Study Sponsors: <i>Same as current</i></div><div>Collaborators:<div><div>• Immune Tolerance Network (ITN)</div><div>• PPD</div><div>• Rho Federal Systems Division, Inc.</div></div></div></div><div><div>Study Start: April 22, 2021</div><div>Primary Completion: April 2025 (Final data collection date for primary outcome measure)</div><div>Study Completion: March 2028</div><div>First Posted: August 31, 2018</div><div>Results First Posted:</div><div>Last Update Posted: September 14, 2022</div></div></div><div>Secondary Outcome Measures:</div></div> |                 |            |                       |       |



|    | NCT Number  | Title  | Other Names  | Status     | Conditions  | Interventions  | Characteristics  | Population   | Sponsor/Collaborators  | Dates   |
|----|-------------|--|--|------------|---|--|--|--|--|---|
| 22 | NCT05239143 | <a href="#">P-MUC1C-ALLO1 Allogeneic CAR-T Cells in the Treatment of Subjects With Advanced or Metastatic Solid Tumors</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids: P-MUC1C-ALLO1-001 | Recruiting | <ul style="list-style-type: none"><li>Breast Cancer</li><li>Ovarian Cancer</li><li>Non Small Cell Lung Cancer</li><li>Colorectal Cancer</li><li>Pancreatic Cancer</li><li>Renal Cell Carcinoma</li><li>Nasopharyngeal Cancer</li><li>Head and Neck Squamous Cell Carcinoma</li><li>Gastric Cancer</li></ul> | <ul style="list-style-type: none"><li>Biological: P-MUC1C-ALLO1 CAR-T cells<br/>P-MUC1C-ALLO1 is an allogeneic CAR-T cell therapy designed to target cancer cells expressing MUC1-C.</li><li>Drug: Rimiducid<br/>Rimiducid (safety switch activator) may be administered as indicated.</li></ul> | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: Non-Randomized<br>Intervention Model: Sequential Assignment<br>Intervention Model Description:<br>Open label, 3 + 3 design of dose-escalating cohorts with open label, dose expansion at recommended phase 2 dose (RP2D)<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: Not Provided | Actual Enrollment:<br><br>Estimated Enrollment: 100<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years and older (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided | Study Start: February 15, 2022<br><br>Primary Completion: April 2026 (Final data collection date for primary outcome measure)<br><br>Study Completion: April 2039<br><br>First Posted: February 14, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 13, 2022 |

|    | NCT Number  | Title  | Other Names  | Status     | Conditions          | Interventions   | Characteristics  | Population   | Sponsor/Collaborators  | Dates   |
|----|-------------|--|--|------------|---------------------|---|--|--|--|---|
| 23 | NCT04318964 | <a href="#">TAEST16001 in the Treatment of Soft Tissue Sarcoma</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids:<br>SunYat-senU-TAEST16001 | Recruiting | Soft Tissue Sarcoma | <p>Biological: TAEST16001 cells</p> <p>The patients in the dose increasing part and the expanding part received the intravenous reinfusion of TAEST16001 cells on the 5th day (i.e. the interval was 4 days) after the lymphocyte elimination chemotherapy: If the dose level of reinfusion was 1 and 2, the planned total amount of TAEST16001cells (calculated by TCR-T positive cells) was given a single reinfusion on the 1st day of the study. If the dose level of reinfusion was 3 and 4,then the total amount of TAEST16001cells (calculated by TCR-T positive cells) was planned to be reinjected in 60% and 40% proportion on the first and second day of the study.</p> <p>After the first reinfusion of TAEST16001 cells, the patients will be given a small dose of IL-2 subcutaneously (study day 1 to day 14), 500000 U / time. The first injection will be carried out within 30 minutes after the cell reinfusion, twice a day (interval 10-12 hours), for 14 days.</p> | <p>Study Type: Interventional</p> <hr/> <p>Phase: Phase 1</p> <hr/> <p>Study Design: Allocation: N/A<br/>Intervention Model: Single Group Assignment<br/>Masking: None (Open Label)<br/>Primary Purpose: Treatment</p> <hr/> <p>Primary Outcome Measures: <i>Same as current</i></p> <hr/> <p>Secondary Outcome Measures:</p> <ul style="list-style-type: none"><li>Peripheral blood TAEST16001 cell peak (C Max) [ Time Frame: Time Frame: From cell infusion up to 28 days ]<br/><br/>The maximum concentration of TAEST16001 cells observed in peripheral blood, and TAEST16001 cells were detected by flow cytometry and TCR-T DNA was detected by qPCR</li><li>Peripheral blood TAEST16001 cell peak time (T Max) [ Time Frame: Time Frame: From cell infusion up to 28 days ]<br/><br/>The time required to observe maximum concentration of TAEST16001 cells in peripheral blood, TAEST16001 cells were detected by flow cytometry and TCR-T DNA was detected by qPCR</li><li>Peripheral blood TAEST16001 cell AUC 0-28 [ Time Frame: Time Frame: From cell infusion up to 28 days ]<br/><br/>Area under the Concentration-time Curve from Zero up to a Definite Time Day 28</li><li>T cell subsets [ Time Frame: Time Frame: From cell infusion up to 28 days ]<br/><br/>5mL venous blood was collected and sent to the center for flow cytometry</li><li>Peripheral blood antigen-specific CTL [ Time Frame: Time Frame: From cell infusion up to 28 days ]<br/><br/>5mL venous blood was collected and sent to the center for flow cytometry of cytotoxic T Cell</li><li>Effector cell activity [ Time Frame: Time Frame: From cell infusion up to 28 days ]<br/><br/>5mL venous blood was collected and sent to the center for flow cytometry of cytokines secreted by effector cells</li></ul> | <p>Actual Enrollment:</p> <hr/> <p>Estimated Enrollment: 12</p> <hr/> <p>Original Estimated Enrollment: <i>Same as current</i></p> <hr/> <p>Age: 18 Years to 70 Years (Adult, Older Adult)</p> <hr/> <p>Sex: All</p> | <p>Study Sponsors: <a href="#">Same as current</a></p> <hr/> <p>Collaborators: Guangdong Xiangxue Precision Medical Technology Co., Ltd.</p> | <p>Study Start: March 19, 2020</p> <hr/> <p>Primary Completion: November 1, 2022 (Final data collection date for primary outcome measure)</p> <hr/> <p>Study Completion: March 1, 2023</p> <hr/> <p>First Posted: March 24, 2020</p> <hr/> <p>Results First Posted:</p> <hr/> <p>Last Update Posted: September 15, 2022</p> |

|    | NCT Number  | Title  | Other Names   | Status                 | Conditions  | Interventions  | Characteristics   | Population  | Sponsor/Collaborators  | Dates  |
|----|-------------|--|---|------------------------|---|--|---|---|--|--|
| 24 | NCT05539183 | <a href="#">Collection of Pleural Effusion Fluid</a><br><br>Study Documents:   | Title Acronym:<br><br>Other Ids:<br>22151PLEUREF        | Not yet recruiting     | <ul style="list-style-type: none"><li>• Solid Tumor</li><li>• Pleural Effusion</li><li>• Metastasis</li></ul> | Procedure: Blood withdrawal<br>Blood withdrawal  | Study Type: Interventional<br><br>Phase: Not Applicable<br><br>Study Design: Allocation: N/A<br>Intervention Model: Single Group Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Basic Science<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: <i>Same as current</i> | Actual Enrollment:<br><br>Estimated Enrollment: 50<br><br>Original Estimated Enrollment: <i>Same as current</i><br><br>Age: 18 Years and older (Adult, Older Adult)<br><br>Sex: All | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Vrije Universiteit Brussel | Study Start: October 1, 2022<br><br>Primary Completion: December 31, 2024 (Final data collection date for primary outcome measure)<br><br>Study Completion: December 31, 2025<br><br>First Posted: September 14, 2022<br><br>Results First Posted:<br><br>Last Update Posted: September 14, 2022 |
| 25 | NCT03602612 | <a href="#">T Cells Expressing a Novel Fully-Human Anti-BCMA CAR for Treating Multiple Myeloma</a><br><br>Study Documents: | Title Acronym:<br><br>Other Ids:<br>180125<br>18-C-0125 | Active, not recruiting | <ul style="list-style-type: none"><li>• Myeloma-Multiple</li><li>• Myeloma, Plasma-Cell</li></ul>             | <ul style="list-style-type: none"><li>• Drug: Cyclophosphamide<br/>300 mg/m^2 IV over 30 minutes on days -5, -4, and -3</li><li>• Drug: Fludarabine<br/>30 mg/m^2 IV infusion over 30 minutes administered immediately following the cyclophosphamide on day -5, -4, -3</li><li>• Biological: Anti-BCMA CAR T cells<br/>0.75x10^6 - 12.0X10^6 CAR+ T cells per kg of recipient bodyweight one time dose on day 0</li></ul> | Study Type: Interventional<br><br>Phase: Phase 1<br><br>Study Design: Allocation: Non-Randomized<br>Intervention Model: Sequential Assignment<br>Masking: None (Open Label)<br>Primary Purpose: Treatment<br><br>Primary Outcome Measures: <i>Same as current</i><br><br>Secondary Outcome Measures: Not Provided             | Actual Enrollment: 35<br><br>Estimated Enrollment:<br><br>Original Estimated Enrollment: 42<br><br>Age: 18 Years to 73 Years (Adult, Older Adult)<br><br>Sex: All                   | Study Sponsors: <a href="#">Same as current</a><br><br>Collaborators: Not Provided               | Study Start: September 14, 2018<br><br>Primary Completion: January 1, 2023 (Final data collection date for primary outcome measure)<br><br>Study Completion: January 1, 2024<br><br>First Posted: July 27, 2018<br><br>Results First Posted:<br><br>Last Update Posted: September 19, 2022       |