

Phase I and Phase II Clinical Trials: Hematology, Oncology, and Stem Cell Transplantation

Contacts

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Oncology: Leukemia/Lymphoma

NCT #/Phase	Title	Led by	Investigator	Contact
Phase I-II (NCT05848687)	TINI 2: Total Therapy for Infants with Acute Lymphoblastic Leukemia II	Stanford	Tanja Gruber	Tanja Gruber, MD, PhD, tagruber@stanford.edu
Phase I (NCT05188170)	Phase 1 Study of Niclosamide in Pediatric and Young Adults Patients with Relapsed and Refractory AML	Stanford	Kathleen Sakamoto	Stefania Chirita, schirita@stanford.edu
Phase I (NCT05101551)	PARPAML: A Phase 1 Protocol for Relapsed Pediatric AML to Determine the Safety and Efficacy of the PARP Inhibitor Talazoparib in Combination with Chemotherapy	POETIC	Norman Lacayo	Stefania Chirita, schirita@stanford.edu
Phase II (NCT06317662)	AALL2321: A Phase 2 Study of Blinatumomab in Combination with Chemotherapy for Infants with Newly Diagnosed Acute Lymphoblastic Leukemia with Randomization of KMT2A-Rearranged Patients to Addition of Venetoclax	COG	Jay Balagtas	Stefania Chirita, schirita@stanford.edu
Phase II (NCT02981628)	AALL1621: A Phase 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND# 133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)	COG	Jay Balagtas	Stefania Chirita, schirita@stanford.edu
Phase II (NCT05828069)	ANHL2121: Phase 2 Study of Tovorafenib (DAY101) in Relapsed and Refractory Langerhans Cell Histiocytosis	COG	Jay Balagtas	Stefania Chirita, schirita@stanford.edu
Phase II (NCT04554914)	A Study to Evaluate Tabelecleucel in Participants With Epstein-barr Virus-associated Diseases	Atara Biotherapeutics	Lianna Marks	Chloe Ordonez, RN, cordona@stanford.edu

Oncology: Immunotherapy

NCT #/Phase	Title	Led by	Investigator	Contact
Phase I (NCT07087002)	Phase 1 Clinical Trial of GPC2 Chimeric Antigen Receptor T (GPC2 CAR T) Cells for Relapsed or Refractory Medulloblastoma in Children and Young Adults	Stanford	Katie Ryan	Mariah Duncan, m1duncan@stanford.edu
Phase I (NCT06500819)	Phase 1 Clinical Trial Of Autologous B7-H3 Chimeric Antigen Receptor T Cells (B7-H3cart) In Children And Young Adults With Relapsed Or Refractory Solid Tumor Expressing B7-H3 Target	Stanford	Sneha Ramakrishna	Amy Li, ali4@stanford.edu
Phase I/Ib (NCT06408194)	Phase I/Ib Clinical Trial of Autologous CD22 Chimeric Antigen Receptor (CAR) T cells following Commercial CD19 CAR T cells in Children and Young Adults with Recurrent or Refractory B Cell Malignancies	Stanford	Kara Davis	Michelle Fujimoto, mfujimot@stanford.edu
Phase I (NCT04196413)	Phase I Clinical Trial of Autologous GD2 Chimeric Antigen Receptor (CAR) T cells (GD2CART) for Diffuse Intrinsic Pontine Gliomas (DIPG) and Spinal Diffuse Midline Glioma (DMG)	Stanford	Crystal Mackall and Michelle Monje	Bryce Igawa, bigawa@stanford.edu
Phase I/II (NCT05642455)	A Phase 1/2, Open-Label, Basket Study to Assess the Safety, Tolerability, and Anti-Tumor Activity of Afamitresgene Autoleucl in Pediatric Subjects with MAGE-A4 Positive Tumors	Adapt-immune	Sneha Ramakrishna	Amy Li, ali4@stanford.edu
Phase I (NCT04539366)	GD2-CAR PERSIST: Production and Engineering of GD2-Targeted, Receptor Modified T Cells (GD2CART) for Osteosarcoma or Neuroblastoma to Increase Systemic Tumor Exposure	PED-CITN	Jay Balagtas	Amy Li, ali4@stanford.edu

Oncology: Neuro-Oncology

NCT #/Phase	Title	Led by	Investigator	Contact
Phase I/II (NCT05099003)	ACNS1821: A Phase 1/2 Trial of Selinexor (KPT-330) and Radiation Therapy in Newly-Diagnosed Pediatric Diffuse Intrinsic Pontine Glioma (DIPG) and High-Grade Glioma (HGG)	National Cancer Institute	Jay Balagtas	Elisabeth Merkel, RN, merkel@stanford.edu
Phase II (NCT05535166)	SJiMB21: Phase 2 Study of Molecular and Clinical Risk-Directed Therapy for Infants and Young Children with Newly Diagnosed Medulloblastoma	St. Jude	Sonia Partap	Elisabeth Merkel, RN, merkel@stanford.edu
Phase II (NCT04696029)	BCC016: Phase II Trial of Eflornithine/DFMO as Maintenance Therapy for Molecular High Risk/Very High Risk and Relapsed/Refractory Medulloblastoma	Beat Childhood Cancer Research Consortium	Raya Saab	Elisabeth Merkel, RN, merkel@stanford.edu
Phase II (NCT06368817)	ACNS2321: A Phase II Trial Evaluating Chemotherapy followed by Response-Based Reduced Radiation Therapy for Patients with Central Nervous System Germinomas	COG	Jay Balagtas	Elisabeth Merkel, RN, merkel@stanford.edu
Phase II (NCT04684368)	ACNS2021: Phase 2 Trial of Chemotherapy followed by Response-Based Whole Ventricular & Spinal Canal Irradiation (WVSCI) for Patients with Localized Non-Germinomatous Central Nervous System Germ Cell Tumor	COG	Jay Balagtas	Elisabeth Merkel, RN, merkel@stanford.edu
Phase I/II (NCT04774718)	GO42286: A Phase I/II, Open-Label, Multicenter Study Evaluating the Safety, Pharmacokinetics, and Efficacy of Alectinib in Pediatric Patients w/ ALK-Fusion-Positive Solid or CNS Tumors for whom Prior Treatment has Proven to be Ineffective or for who there is no satisfactory treatment available	Genentech	Sonia Partap	Elisabeth Merkel, RN, merkel@stanford.edu

Oncology: Solid Tumors

NCT #/Phase	Title	Led by	Investigator	Contact
Phase II (NCT04616560)	PEPN1924: A Phase 2 Study of DS-8201A (NSC# 807708, IND# 153036) in Adolescents, or Young Adults with Recurrent HER2+ Osteosarcoma	NCI	Lianna Marks	Stefania Chirita, schirita@stanford.edu
Phase II (NCT06023641)	RMS2021, A Protocol for the Treatment of Newly Diagnosed Rhabdomyosarcoma Using Molecular Risk Stratification and Liposomal Irinotecan Based Therapy in Children with Intermediate- and High-Risk Disease	St. Jude	Raya Saab	Caroline Caballero, cgc10@stanford.edu
Phase I/II (NCT04901702)	A Randomized Phase I/II study of Onivyde in combination with Talazoparib or Temozolomide in children and young adults with recurrent solid malignancies and Ewing sarcoma	St. Jude	Allison Pribnow	Richard Fu, yjfu@stanford.edu
Phase I/II (NCT05634369)	A Multi-Institution Study of TGFβ imprinted, Ex Vivo Expanded Universal Donor NK Cell Infusions as Adoptive Immunotherapy in Combination with Gemcitabine and Docetaxel in Patients with Relapsed or Refractory Pediatric Bone and Soft Tissue Sarcomas: The TiNKS Trial	Nationwide Children's Hospital	Raya Saab	Richard Fu, yjfu@stanford.edu
Phase II (NCT05985161)	A Multi-Center Phase II Study of Selinexor in Treating Recurrent or Refractory Wilms Tumor and Other Pediatric Solid Tumors	MSKCC	Chelsey Burke	Caroline Caballero, cgc10@stanford.edu
Phase II (NCT05504291)	ARET2121: Intravitreal Melphalan for Intraocular Retinoblastoma	COG	Jay Balagtas	Richard Fu, yjfu@stanford.edu
Phase II (NCT04322318)	AREN1921: A Study of Combination Chemotherapy for Patients With Newly Diagnosed DAWT and Relapsed FHWT	COG	Jay Balagtas	Chloe Ordon, RN, cordona@stanford.edu
Phase I/II (NCT05286801)	A Phase 1/2 Study of Tiragolumab (NSC# 827799, IND# 161266) and Atezolizumab (NSC# 783608, IND# 161266) in Patients with Relapsed or Refractory SMARCB1 or SMARCA4 Deficient Tumors	COG	Jay Balagtas	Chloe Ordon, RN, cordona@stanford.edu
Phase I (NCT06441331)	A Multi-center, Open-label, Interventional Phase I Trial to Determine the Dose and Evaluate the Pharmacokinetics (PK) and Safety of Lutetium Lu 177 Edotreotide Targeted Radiopharmaceutical Therapy (RPT) as Monotherapy or Following Standard of Care (SoC) for the Treatment of Somatostatin Receptor-positive Tumors in the Pediatric Population (KinLET)	ITM Solucin GmbH	Raya Saab	Kailee Tanaka, kltanaka@stanford.edu
Phase I/II (NCT05734066)	A phase 1/2, open-label study to evaluate the safety, tolerability, pharmacokinetics (PK), recommended phase 2 dose (RP2D), and efficacy of lurbinectedin monotherapy in pediatric participants with previously treated solid tumors followed by expansion to assess efficacy and safety in pediatric and young adult participants with relapsed/refractory Ewing sarcoma	Jazz Pharmaceuticals	Allison Pribnow	Richard Fu, yjfu@stanford.edu

Stem Cell Transplantation and Gene Therapy

NCT #/Phase	Title	Led by	Investigator	Contact	Condition Treated
Phase I (NCT06986382)	Phase 1b/2a Trial of Allogeneic HSCT From an HLA-partially Matched Related or Unrelated Donor After TCRab+ T-cell/CD19+ B-cell Depletion for Patients With Monogenic and/or Early-onset Medically Refractory Crohn Disease	Stanford	Jessie Alexander	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase I/II (NCT06909110)	Viral Specific T-Lymphocytes by Cytokine Capture System (CCS) to Treat Infection With Adenovirus or Cytomegalovirus After Hematopoietic Cell Transplantation or Solid Organ Transplantation and in Patients With Compromised Immunity	Stanford	Jessie Alexander	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase I/II (NCT05508009)	Phase 1b/2a trial of allogeneic hematopoietic stem cell transplantation (HSCT) from an HLA-partially matched related or unrelated donor after TCRαβ + T-cell/CD19+ B-cell depletion for patients who will receive a kidney transplant (KT) from the same HSCT donor	Stanford	Alice Bertaina and Paul Grimm	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase I (NCT05241444)	Phase I Study of Autologous CD4⁺LVFOXP3 in Participants With Immune Dysregulation Polyendocrinopathy Enteropathy X-linked (IPEX) Syndrome	Stanford	Rajni Agarwal and Rosa Bacchetta	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase 1B/2A (NCT04784052)	TCRab+T-CELL/CD19+B depleted Hematopoietic Grafts and A Reduced-Intensity Preparative Conditioning Regimen Containing Briquilimab to Achieve Engraftment and Blood Reconstitution in Patients with Fanconi Anemia	Stanford	Rajni Agarwal	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase II (NCT04249830)	Allogeneic hematopoietic stem cell transplantation from an HLA-partially matched related or unrelated donor after TCR αβ+T cells/CD19+ B cell depletion in children and young adults affected by malignant or non-malignant hematological disorders	Stanford	Alice Bertaina	DL-SCTIntakeCoordinators@stanfordchildrens.org	Hematologic malignancies and non-malignant disorders

NCT #/Phase	Title	Led by	Investigator	Contact	Condition Treated
Phase I (NCT04640987)	A Study of T-alo10 Infusion After HLA-Partially Matched Related or Unrelated TCR $\alpha\beta$+ T-cell/ CD19+ B-cell Depleted Allogeneic Hematopoietic Stem Cell Transplantation ($\alpha\beta$ Depleted-HSCT) in Children and Young Adults Affected by Hematologic Malignancies	Stanford	Alice Bertaina	DL-SCTIntakeCoordinators@stanfordchildrens.org	Hematologic malignancies
Phase I/II (NCT04819841)	Gene Correction in Autologous CD34+ Hematopoietic Stem Cells (HbS to HbA) to Treat Severe Sickle Cell Disease (RESTORE)Study	Kamau Therapeutics	David Shyr	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase 2 (NCT03619551)	A randomized trial of low versus moderate exposure busulfan for infants with severe combined immunodeficiency (SCID) receiving TCRab+/CD19+ depleted transplantation: A Phase II Study	Pediatric Blood and Marrow Transplant Consortium	Alice Bertaina	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders