

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 (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	Stanford	Jennifer Kamens	Sophia Brodsky RN, sophia.brodsky@stanford.edu
Phase I (NCT04996160)	Palbociclib in Combination With Chemotherapy in Pediatric Patients With Relapsed or Refractory Acute Lymphoblastic Leukemia (RELPALL2)	Stanford	Tanja Gruber	Sophia Brodsky, RN, sophia.brodsky@stanford.edu
Phase I (NCT05188170)	Phase 1 Study of Niclosamide in Pediatric and Young Adults Patients with Relapsed and Refractory AML	Stanford	Kathleen Sakamoto	Sophia Brodsky, RN, sophia.brodsky@stanford.edu
Phase II (NCT03755804)	Pediatric Classical Hodgkin Lymphoma Consortium Study: cHOD17	St. Jude	Michael Link	Stefania Chirita, schirita@stanford.edu
Coming soon (NCT02932280)	POE 16-01: A Phase I/II study of Neratinib in Pediatric Patients with Relapse/Refractory Solid Tumors or Hematologic Malignancies	POETIC	Norman Lacayo	Stefania Chirita, schirita@stanford.edu
Phase II (NCT02981628)	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 (NCT03190915)	A Phase 2 Study of the MEK inhibitor Trametinib (IND #119346, NSC# 763093) in Children with Relapsed or Refractory Juvenile Myelomonocytic Leukemia	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 Ordon, RN, cordona@stanford.edu

Oncology: Immunotherapy

NCT #/Phase	Title	Led by	Investigator	Contact
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	Christina Baggott, PhD, baggott@stanford.edu
Phase IB (NCT04088864)	Phase IB Clinical Trial of Autologous CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults With Recurrent or Refractory B Cell Malignancies (GENE TRANSFER)	Stanford	Liora Schultz	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT03241940)	Phase 1 Dose Escalation Study of CD19/CD22 Chimeric Antigen Receptor (CAR) T Cells in Children and Young Adults with Recurrent or Refractory B Cell Malignancies	Stanford	Crystal Mackall	Christina Baggott, PhD, baggott@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	Sneha Jariwala, snehaj@stanford.edu
Phase I (NCT04751383)	Phase 1 Trial of Hu5F9-G4 (Magrolimab) Combined With Dinutuximab in Children and Young Adults With Relapsed and Refractory Neuroblastoma or Relapsed Osteosarcoma (PED-CITN-03)	PED-CITN	Jay Balagtas	Sneha Jariwala, snehaj@stanford.edu
Phase II (NCT03876769)	AALL1721/CASSIOPEIA: A phase II trial of tisagenlecleucel in first-line high-risk (HR) pediatric and young adult patients with B-cell acute lymphoblastic leukemia (B-ALL) who are minimal residual disease (MRD) positive at the end of consolidation (EOC) therapy	Novartis/COG	Kara Davis	Christina Baggott, PhD, baggott@stanford.edu

Oncology: Neuro-Oncology

NCT #/Phase	Title	Led by	Investigator	Contact
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	Tiffany Tang, tiffanytang@stanford.edu
Phase II (NCT03919071)	ACNS1723: Phase 2 Study of Dabrafenib (NSC# 763760) with Trametinib (NSC# 763093) after Local Irradiation in Newly-Diagnosed BRAFV600-Mutant High-Grade Glioma (HGG) (IND# 145355)	COG	Jay Balagtas	Tiffany Tang, tiffanytang@stanford.edu
Phase II (NCT02724579)	A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma (ACNS1422)	COG	Jay Balagtas	Tiffany Tang, tiffanytang@stanford.edu

NCT #/Phase	Title	Led by	Investigator	Contact
Phase I/II (NCT04201457)	PBTC-055: Phase I/II trial of Dabrafenib, Trametinib, and Hydroxychloroquine (HCQ) for BRAF V600E-mutant or Trametinib and HCQ for BRAF fusion/duplication positive or NF1-associated recurrent or progressive gliomas in children and young adults	PBTC	Sonia Partap	Tiffany Tang, tiffanytang@stanford.edu
Phase I/II (NCT03904862)	PBTC-053: A Pediatric Brain Tumor Consortium Phase I/ II and Surgical Study of CX-4945 in Patients with Recurrent SHH Medulloblastoma	PBTC	Sonia Partap	Stefania Chirita, schirita@stanford.edu
Phase I (NCT03598244)	PBTC-049: A Phase I study of Savolitinib in Recurrent, Progressive or Refractory Medulloblastoma, High-Grade Glioma, or Diffuse Intrinsic Pontine Glioma	PBTC	Sonia Partap	Elisabeth Merkel, RN, merkel@stanford.edu
Feasibility Study (NCT03033992)	PBTC-048: Feasibility trial of Optune for children with recurrent or progressive supratentorial high-grade glioma and ependymoma	PBTC	Sonia Partap	Stefania Chirita, schirita@stanford.edu
Phase I/II (NCT02359565)	PBTC-045: A Safety and Preliminary Efficacy trial of MK-3475 (pembrolizumab; anti-PD-1) in Children with recurrent, progressive or refractory high-grade gliomas (HGG), DIPGs and hypermutated brain tumors	PBTC	Sonia Partap	Stefania Chirita, schirita@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
Phase I/II (NCT02359565)	PBTC-045: A Safety and Preliminary Efficacy trial of MK-3475 (pembrolizumab; anti-PD-1) in Children with recurrent, progressive or refractory high-grade gliomas (HGG), DIPGs and hypermutated brain tumors	PBTC	Sonia Partap	Stefania Chirita, schirita@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 I/II (NCT02932280)	POE 16-01: A Phase I/II study of Neratinib in Pediatric Patients with Relapse/Refractory Solid Tumors or Hematologic Malignancies	POETIC	Norman Lacayo	Stefania Chirita, schirita@stanford.edu
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 (NCT04195399)	A Safety, Pharmacokinetic and Efficacy Study of a γ-Secretase Inhibitor, Nirogacestat (PF-03084014; IND# 146375), in Children and Adolescents with Progressive, Surgically Unresectable Desmoid Tumors	COG	Jay Balagtas	Chloe Ordon, RN, cordona@stanford.edu
Phase II (NCT037943490)	A Phase 2 Randomized Study of Irinotecan/ Temozolomide/Dinutuximab with or without Eflornithine (DFMO) (IND# 141913) in Children with Relapsed, Refractory or Progressive Neuroblastoma (ANBL1821)	COG	Jay Balagtas	Chloe Ordon, RN, cordona@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 (NCT04029688)	IDASA: A Phase I/II, Multicenter, Open-Label, Multi-Arm Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Preliminary Activity of Idasanutlin In Combination with Either Chemotherapy or Venetoclax in the Treatment of Pediatric and Young Adult Patients with Relapsed/ Refractory Acute Leukemias or Solid Tumors	Genentech	Norman Lacayo	Stefania Chirita, schirita@stanford.edu
Phase I (NCT03478462)	Collectar: A Phase 1, Open-Label, Dose Escalation Study of CLR 131 in Children and Adolescents with Select Solid Tumors, Lymphoma, and Malignant Brain Tumors	Collectar	Norman Lacayo	Chloe Ordon, RN, cordona@stanford.edu
Phase I/II (NCT03899792)	A Phase 1/2 Study of the Oral RET Inhibitor LOXO-292 in Pediatric Patients with Advanced RET-Altered Solid or Primary Central Nervous System Tumors	Loxo	Sheri Spunt	Chloe Ordon, RN, cordona@stanford.edu
Phase II (NCT03709680)	ADVL1921: Phase 1 study to evaluate the safety and pharmacokinetics of palbociclib (IBRANCE®) in combination with irinotecan and temozolomide in pediatric patients with recurrent or refractory solid tumors	COG/ Pfizer	Jay Balagtas	Chloe Ordon, RN, cordona@stanford.edu

Stem Cell Transplantation and Gene Therapy

NCT #/Phase	Title	Led by	Investigator	Contact	Condition Treated
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 TCR$\alpha\beta$ + 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 JSP191 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 $\alpha\beta$+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
Phase I (NCT04640987)	A Study of T-allo10 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 (NCT03198234)	Use of T-allo10 cell infusions combined with mismatched related or unrelated donor hematopoietic stem cell transplantation (HSCT) for hematological malignancies	Stanford	Rajni Agarwal-Hashmi	DL-SCTIntakeCoordinators@stanfordchildrens.org	Hematologic malignancies
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 (CSIDE)	Pediatric Blood and Marrow Transplant Consortium	Alice Bertaina	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders

NCT #/Phase	Title	Led by	Investigator	Contact	Condition Treated
Phase II (NCT02646839)	KIR Favorable Mismatched Haplo Transplant and KIR Polymorphism in ALL/AML/MDS Allo-HCT Children	Pediatric Blood and Marrow Transplant Consortium	Alice Bertaina	DL-SCTIntakeCoordinators@stanfordchildrens.org	Hematologic malignancies
Phase II (NCT04248439)	A Phase II Clinical Trial to Evaluate the Safety of the Infusion of Autologous CD34+ Cells Transduced with a Lentiviral Vector Carrying the FANCA Gene in Pediatric Subjects with Fanconi Anemia Subtype-A	Rocket Pharmaceuticals	Rajni Agarwal	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase II (NCT04693637)	Posoleucel (ALVR105, Formerly Viralm-M) for Multi-Virus Prevention in Patients Post-Allogeneic Hematopoietic Cell Transplant (Prevent)	AlloVir	Orly Klein	DL-SCTIntakeCoordinators@stanfordchildrens.org	Hematologic malignancies and non-malignant disorders
Phase III (NCT05179057)	Phase 3, Randomized, Double-Blind, Placebo-Controlled Trial, with Cross-Over, of Posoleucel (ALVR105) for the Treatment of Adenovirus Infection in Pediatric and Adult Participants Receiving Standard of Care Following Allogeneic Hematopoietic Cell Transplantation	AlloVir	Orly Klein	DL-SCTIntakeCoordinators@stanfordchildrens.org	Hematologic malignancies and non-malignant disorders
Phase I (NCT02963064)	A Study to Evaluate the Safety and Tolerability of Tandemly Purified Allogeneic CD34+ CD90+ Hematopoietic Stem Cells (HSC) Administered Following Conditioning with AMG 191 to Achieve Engraftment and Immune Reconstitution in Patients with Severe Combined Immunodeficiency (SCID)	Jasper Therapeutics	Rajni Agarwal-Hashmi	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders
Phase I (NCT04105166)	Gene Therapy for Pyruvate Kinase Deficiency (PKD): A Phase I Clinical Trial to Evaluate the Safety of the Infusion of Autologous CD34 Cells Transduced with a Lentiviral Vector Carrying the Codon Optimized Red Cell Pyruvate Kinase (coRPK) Gene in Adult and Pediatric Subjects with PKD. (GENE TRANSFER)	Rocket Pharmaceuticals	Ami Shah	DL-SCTIntakeCoordinators@stanfordchildrens.org	Non-malignant disorders