



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

Contacts

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Oncology: Leukemia/Lymphoma

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II/III (coming soon)	TOT17: Total Therapy XVII for Newly Diagnosed Patients With Acute Lymphoblastic Leukemia and Lymphoma	St. Jude	Norman Lacayo	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase II (NCT03164057)	AML16: Phase II Trial of Epigenetic Priming in Patients with Newly Diagnosed Acute Myeloid Leukemia	St. Jude	Norman Lacayo	Christin New, newc@stanford.edu
Phase I (NCT03194932)	A Phase I and Expansion Cohort Study of Venetoclax in Combination with Chemotherapy in Pediatric Patients with Refractory or Relapsed Acute Myeloid Leukemia	St. Jude	Norman Lacayo	Eileen Monge, RN, emonge@stanford.edu
Phase I (NCT02553460)	TINI: Total Therapy for Infants with Acute Lymphoblastic Leukemia (ALL)	St. Jude	Norman Lacayo	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase II (NCT03755804)	Pediatric Classical Hodgkin Lymphoma Consortium Study: cHOD17	St. Jude	Michael Link	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase I (NCT02512926)	POE 14-01: Study of Carfilzomib in combination with Cyclophosphamide and Etoposide for Children with Relapsed or Refractory Solid Tumors and Leukemias	POETIC	Norman Lacayo	Eileen Monge, RN, emonge@stanford.edu
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	Eileen Monge, RN, emonge@stanford.edu
Phase II (NCT01979536)	ANHL12P1: A Randomized Phase II Trial of Brentuximab Vedotin or Crizotinib in Combination with Chemotherapy for Newly Diagnosed Patients with Anaplastic Large Cell Lymphoma (ALCL)	COG	Jay Balagtas	Nancy Sweeters, RN, nancy.sweeters@stanford.edu

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I (NCT03792256)	A Phase 1 Study of Palbociclib (IND#141416), a CDK 4/6 Inhibitor, in Combination with Chemotherapy in Children with Relapsed Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LL)	COG	Jay Balagtas	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase I (NCT03181126)	A Phase 1 Dose Escalation, Open-Label Study of Venetoclax in Combination with Navitoclax and Chemotherapy in Subjects with Relapsed Acute Lymphoblastic Leukemia	AbbVie	Norman Lacayo	Eileen Monge, RN, emonge@stanford.edu
Phase I/II (NCT02703272)	LYM3003: A Randomized, Open-label, Safety and Efficacy Study of Ibrutinib in Pediatric and Young Adult Patients With Relapsed or Refractory Mature B-cell non-Hodgkin Lymphoma	Janssen	Michael Link	Nancy Sweeters, RN, nancy.sweeters@stanford.edu

Oncology: Immunotherapy

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I	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 II (NCT02900976)	ANHL1522: A Pilot Study of Rituximab (RTX) and Third Party Latent Membrane Protein (LMP)-specific Cytotoxic T-Lymphocytes (LMP-TC, IND # 17068) in Pediatric Solid Organ Recipients (SOT) with EBV-Positive CD20-Positive Post-Transplant Lymphoproliferative Disease (PTLD)	COG	Jay Balagtas	Christin New newc@stanford.edu
Phase I (NCT03904069, coming soon)	CCT5027: A Phase 1 Study Evaluating the Safety, Tolerability, and Efficacy of FLT3 Chimeric Antigen Receptor T-cell (CAR-T) AMG 553 in Subjects With Relapsed/Refractory Acute Myeloid Leukemia	Janssen	Lori Muffly, Liora Schultz	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT03384654)	An Open-label, Multicenter, Phase 2 Study Evaluating the Efficacy and Safety of Daratumumab in Pediatric and Young Adult Subjects ≥ 1 and ≤ 30 Years of Age With Relapsed/Refractory Precursor B-cell or T-cell Acute Lymphoblastic Leukemia or Lymphoblastic Lymphoma	Janssen	Liora Schultz	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02228096)	CCTL019B2202: A Phase II, single arm, multicenter trial to determine the efficacy and safety of CTL019 in pediatric patients with relapsed and refractory B-cell acute lymphoblastic leukemia	Novartis	Kara Davis	Christina Baggott, PhD, baggott@stanford.edu

Oncology: Neuro-Oncology

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II/III (NCT02114229)	SJATRT: Phase 2 Study Of Alisertib as a Single Agent in Recurrent or Progressive Central Nervous System (CNS) Atypical Teratoid Rhabdoid Tumors (AT/RTs) and Extra-CNS Malignant Rhabdoid Tumors (MRTs) and in Combination Therapy in Newly Diagnosed AT/RT	St. Jude	Sonia Partap	Eileen Monge, RN, emonge@stanford.edu
Phase II/III (NCT01878617)	SJMB12: A Clinical and Molecular Risk-Directed Therapy for Newly Diagnosed Medulloblastoma	St. Jude	Sonia Partap	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02867592)	ADVL1622: Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor and Other Rare Tumors	COG	Jay Balagtas	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase II (NCT03581292)	ACNS1721: A Phase 2 Study of Veliparib (ABT-888, IND # 139199) and Local Irradiation, Followed by Maintenance Veliparib and Temozolomide, in Patients with Newly Diagnosed High-Grade Glioma (HGG) without H3 K27M or BRAFV600E Mutations COG	COG	Jay Balagtas	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase I (NCT03389802)	PBTC-051: Phase I Study to Evaluate the Safety and Tolerability of the CD40 Agonistic Monoclonal Antibody APX005M in Pediatric Subjects With Recurrent/ Refractory Brain Tumors and Newly Diagnosed Brain Stem Glioma	PBTC	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu
Feasibility Study (NCT03033992)	PBTC-48: Feasibility trial of Optune for children with recurrent or progressive supratentorial high-grade glioma and ependymoma	PBTC	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu
Phase I/II (NCT01089101)	PBTC-029B: A Phase I and Phase II and Re-Treatment Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma	PBTC	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu
Phase I/II (NCT02255461)	PBTC-042: Phase I study of CDK 4-6 inhibitor PD-0332991 in children with recurrent, progressive or refractory central nervous system tumors	PBTC	Michelle Monje	Eileen Monge, RN, emonge@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	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu
Phase I/II (NCT02717455)	PBTC-047: Phase 1 Trial of Panobinostat in Children with Diffuse Intrinsic Pontine Glioma	PBTC	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II (NCT01964300)	PBTC-39: Phase II study of Peginterferon alfa-2b (SYLATRON) for pediatric patients with unresectable or recurrent craniopharyngioma	PBTC	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu
Phase I (NCT03598244)	PBTC-49: A Phase I study of Savolitinib in Recurrent, Progressive or Refractory Medulloblastoma, High-Grade Glioma, or Diffuse Intrinsic Pontine Glioma	PBTC	Michelle Monje	Eileen Monge, RN, emonge@stanford.edu
Phase IIb (coming soon)	A Phase 2b Trial of the MEK 1/2 Inhibitor (MEKi) PD-0325901 in Adult and Pediatric Patients with Neurofibromatosis Type 1 (NF1)-Associated Inoperable Plexiform Neurofibromas (PNs) that are Progressing or Causing Significant Morbidity	Spring-Works	Cynthia Campen	Nancy Sweeters, RN, nancy.sweeters@stanford.edu
Phase II (NCT03257631)	A Phase 2 Clinical Study of Pomalidomide (CC-4047) Monotherapy for Children and Young Adults with Recurrent or Progressive Primary Brain Tumors	Celgene	Sonia Partap	Nancy Sweeters, RN, nancy.sweeters@stanford.edu

Oncology: Solid Tumors

NCT #/Phase	Title	Sponsor	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	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02512926)	POE 14-01: Phase I Study of Carfilzomib in combination with Cyclophosphamide and Etoposide for Children with Relapsed or Refractory Solid Tumors and Leukemias	POETIC	Norman Lacayo	Eileen Monge, RN, emonge@stanford.edu
Phase II (NCT02867592)	ADVL1622: Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor and Other Rare Tumors	COG	Jay Balagtas	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02452554)	ADVL1322: A Phase II Study of Pazopanib (GW786034, NSC# 737754) in Children, Adolescents and Young Adults with Refractory Solid Tumors	COG	Jay Balagtas	Christina Baggott, PhD, baggott@stanford.edu
Phase I/II (NCT02304458)	ADVL1412: A Phase 1/2 Study of Nivolumab (IND# 124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab	COG	Jay Balagtas	Christina Baggott, PhD, baggott@stanford.edu

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I (coming soon)	Cellectar: A Phase 1, Open-Label, Dose Escalation Study of CLR 131 in Children and Adolescents with Select Solid Tumors, Lymphoma, and Malignant Brain Tumors	Cellectar	Norman Lacayo	Jenny Joaquin, jjoaquin@stanford.edu
Phase I/II (coming soon)	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	Jenny Joaquin, jjoaquin@stanford.edu
Phase II (coming soon)	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	Jenny Joaquin, jjoaquin@stanford.edu

Stem Cell Transplantation

NCT #/Phase	Title	Sponsor	Investigator	Contact
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)	Stanford	Rajni Agarwal-Hashmi	Kyle Kovtun, Kyle.Kovtun@stanford.edu
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	Gopin Saini, gopin.saini@stanford.edu
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	Gopin Saini, gopin.saini@stanford.edu
Phase I/II (NCT03475212)	Antiviral Cellular Therapy for Enhancing T-cell Reconstitution Before or After Hematopoietic Stem Cell Transplantation (ACES)	Pediatric Blood and Marrow Transplant Consortium	Rajni Agarwal-Hashmi	Peter Chase, peter.chase@stanford.edu
Phase I (NCT03814408)	A Phase I 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	Sandeep Soni, Agnieszka Czechowicz	Kyle Kovtun, Kyle.Kovtun@stanford.edu
Expanded Access (NCT02596997)	An Intermediate-Size, Expanded Access Protocol to Provide Brincidofovir for the Treatment of Serious Adenovirus Infection or Disease	Chimerix, Inc.	Rajni Agarwal-Hashmi	Peter Chase, peter.chase@stanford.edu

Hematology

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase 2 (NCT02476916)	A Phase 2, Open Label, Randomized, Dose Ranging, Safety, Efficacy, PK and PD Study of AG-348 in Adult Patients with Pyruvate Kinase Deficiency (AG348-C-003)	Agios	Bert Glader	Elaine Macasiray, RN, emacasiray@stanford.edu
Phase I (NCT02303431)	A Phase I, Open-Label, Single Dose, Non-Randomized Study to Evaluate Pharmacokinetics and Pharmacodynamics of Edoxaban in Pediatric Patients	Daiichi Sankyo	Michael Jeng	Elaine Macasiray, RN, emacasiray@stanford.edu
Phase II (NCT02110069)	SIR-DA-1202: A Randomized Phase 2 Study of Vincristine versus Sirolimus to treat High Risk Kaposiform Hemangioendothelioma (KHE)	Pfizer and Boston Children's Hospital	Michael Jeng	Elaine Macasiray, RN, emacasiray@stanford.edu
Phase II (NCT030256698)	A Phase II, Open-Label, Non-Controlled, Intra-Patient Dose-Escalation Study to Characterize the Pharmacokinetics after Oral Administration of Eltrombopag in Pediatric Patients With Refractory, Relapsed, or Treatment Naive Severe Aplastic Anemia or Recurrent Aplastic Anemia	Novartis and Boston Children's Hospital	Bert Glader	Elaine Macasiray, RN, emacasiray@stanford.edu
Phase II/III (NCT02069899)	A Phase II/III Open-label, Single Arm Multicenter Study to Assess Safety, Tolerability, Pharmacokinetics and Efficacy of Intravenous Multiple Administrations of NI-0501, an Anti-interferon Gamma (Anti-IFN) Monoclonal Antibody in Pediatric Patients with Primary Hemophagocytic Lymphohistiocytosis(HLH)	NovImmune	Michael Jeng	Elaine Macasiray, RN, emacasiray@stanford.edu