

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 I (NCT02553460)	TINI: Total Therapy for Infants with Acute Lymphoblastic Leukemia (ALL)	St. Jude	Norman Lacayo	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT01920932)	HLHR13: Testing the Substitution of Brentuximab Vedotin for Vincristine in the Usual Chemotherapy and Radiation in High-Risk Pediatric Hodgkin Lymphoma	St. Jude	Michael Link	Christina Baggott, PhD, baggott@stanford.edu

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II (NCT02538965)	AAML1522: A Phase II, Multicenter, Single-arm, Open-label Study to Evaluate the Activity, Safety and Pharmacokinetics of Lenalidomine in Pediatric Subjects from 1 to 18 Years of Age with Relapse/ Refractory Acute Myeloid Leukemia	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I/II (NCT02212561)	SELHEM: A Phase I/II Study of the Selective Inhibitor of Nuclear Export Selinexor (KPT-330) in Combination with Fludarabine and Cytarabine in Pediatric Patients with Refractory or Relapsed Leukemia or Myelodysplastic Syndrome	St. Jude	Norman Lacayo	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02676323)	PANAML: A Phase I and Dose Expansion Cohort Study Of Panobinostat in Combination with Fludarabine and Cytarabine In Pediatric Patients with Refractory Or Relapse Acute Myeloid Leukemia or Myelodysplastic Syndrome	St. Jude	Norman Lacayo	Christina Baggott, PhD, baggott@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	Christina Baggott, PhD, baggott@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	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02512926)	POE-14: Phase I Study of Carfilzomib in combination with Cyclophosphamide and Etoposide for Children with Relapsed or Refractory Solid Tumors and Leukemias	POETIC	Norman Lacayo	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02228096)	CCTL019B2205J: 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
Part of 2205J	CCTL019B2206: A multicenter study of apheresis collection of peripheral blood mononuclear cells (PBMC) in patients with CD19 expressing malignancies who could be eligible for a CTL019 clinical research trial	Novartis	Kara Davis	Christina Baggott, PhD, baggott@stanford.edu
Phase II (planned to open 6/17)	AHOD1721: Risk-based, response-adapted, Phase II open-label trial of nivolumab + brentuximab vedotin (N+ Bv) for children, adolescents, and young adults with relapsed/refractory (R/R) CD30 + classic Hodgkin lymphoma (cHL) after failure of first-line therapy, followed by brentuximab + bendamustine (Bv + B) for participants with a suboptimal response. CheckMate 744: CHECKpoint pathway and nivolumab clinical Trial Evaluation	COG/BMS	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu

Oncology: Immunotherapy

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I (NCT02475213)	MacroGenics: A Phase 1, Open-label, Dose Escalation Study of MGA271 in Pediatric Patients with B7-H3-Expressing Relapsed or Refractory Solid Tumors	Macro-Genics	Crystal Mackall	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02228096)	Novartis 2205J: 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) Aypical 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	Christina Baggott, PhD, baggott@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 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	Paul Fisher	Christina Baggott, PhD, baggott@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	Paul Fisher	Christina Baggott, PhD, baggott@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	Paul Fisher	Christina Baggott, PhD, baggott@stanford.edu
Phase I/II (NCT02717455)	PBTC-047: Phase 1 Trial of Panobinostat in Children with Diffuse Intrinsic Pontine Glioma	PBTC	Paul Fisher	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02343406)	INTELLANCE 2: ABT-414 alone or ABT-414 plus temozolomide versus lomustine or temozolomide for recurrent glioblastoma: a randomized phase II study of the EORTC Brain Tumor Group	AbbVie	Sonia Partap	Christina Baggott, PhD, baggott@stanford.edu

Oncology: Solid Tumors

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II (NCT02035137)	NANT 2011-01: A Randomized Phase II Study of 131-1-MIBG vs 131-1-MIBG with Vincristine and Irinotecan vs 131-1-MIBG with Vorinostat for Resistant/Relapsed Neuroblastoma	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT01711554)	NANT2011-04: A Phase I Study of Lenalidomide and Anti-GD2 Mab CH14.18 +/- Isotretinoin in Patients with Refractory/Recurrent Neuroblastoma	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02030964)	NANT2012-01: A Phase I Study of Difluoromethylornithine (DFMO) and Celecoxib Cyclophosphamide/Topotecan for Patients with Relapsed or Refractory Neuroblastoma	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02573896)	NANT 2013-01: Immunotherapy of Relapsed Neuroblastoma with expanded NK cells, Lenalidomide and ch14.18	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02298348)	NANT 2013-02: A Phase I Study of Sorafenib and Cyclophosphamide/Topotecan in Patients with Relapsed and Refractory Neuroblastoma	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02337309)	NANT 2014-01: Phase I Study of SF1126 for Patients with Relapsed or Refractory Neuroblastoma	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I/II	NANT 2015-02: Phase 1/2 Study of PF-06463922, an Oral Small Molecule Inhibitor of ALK/ROS1, for patients with Alk-Driven Relapsed or Refractory Neuroblastoma	NANT	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I/II (NCT02637687)	LOXO: A Phase 1/2 Study of the Oral TRK Inhibitor LOXO 101 in Pediatric Patients with Advanced Solid or Primary Central Nervous System Tumors	Loxo	Sheri Spunt	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	Sheri Spunt	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	Sheri Spunt, Crystal Mackall, Kara Davis	Christina Baggott, PhD, baggott@stanford.edu

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II (NCT02452554)	ADVL1522: A Phase 2 Study of IMGN901 (Lorvotuzumab Mertansine; IND# 126953, NSC# 783609) in Children with Relapsed or Refractory Wilms Tumor, Rhabdomyosarcoma, Neuroblastoma, Pleuropulmonary Blastoma, Malignant Peripheral Nerve Sheath Tumor (MPNST) or Synovial Sarcoma	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02475213)	A Phase 1, Open-Label, Dose Escalation Study of MGA271 in Pediatric Patients with B7-H3-Expressing Relapsed or Refractory Solid Tumors	Macro-Genics	Crystal Mackall	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02306161)	AEWS1221: Randomized Phase II Trial Evaluating the Addition of the IGF-1R Monoclonal Antibody Ganitumab (AMG 479, NSC# 750008, IND# 120449) to Multiagent Chemotherapy for Patients with Newly Diagnosed Metastatic Ewing Sarcoma	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02470091)	AOST1321: Phase II Study of Denosumab (IND# 127430, NSC# 744010), a RANK Ligand Antibody, for Recurrent or Refractory Osteosarcoma	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02484443)	AOST1421: A Phase II Study of Human-Mouse Chimeric Anti-Disialoganglioside Monoclonal Antibody ch14.18 (Dinutuximab, NSC#764038, IND# 4308) in Combination with GM-CSF in Patients with Recurrent Osteosarcoma	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT02487979)	AOST1521: A Phase 2 Study of GPNMB-targeted Antibody-Drug Conjugate, CDX-011 (Glembatumumab Vedotin, CR011-vcMMAE; IND# 128248, NSC# 763737), in Recurrent or Refractory Osteosarcoma	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase II/III (NCT02180867)	ARST1321: Pazopanib Neoadjuvant Trial on Non-Rhabdomyosarcoma Soft Tissue Sarcomas (PAZNTIS): A Phase II/III Randomized Trial of Preoperative Chemoradiation or Preoperative Radiation Plus or Minus Pazopanib (NSC# 737754, IND# 118613)	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase II (NCT01767194)	ANBL1221: A Phase II Randomized Trial of Irinotecan/Temozolomide with Temozolomide (NSC# 683864, IND# 61010) or Chimeric 14.18 Antibody (ch14.18) (NSC# 623408, IND# 4308) in Children with Refractory, Relapsed or Progressive Neuroblastoma	COG	Sheri Spunt	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02512926)	POE-014: Phase I Study of Carfilzomib in combination with Cyclophosphamide and Etoposide for Children with Relapsed or Refractory Solid Tumors and Leukemias	POETIC	Norman Lacayo	Christina Baggott, PhD, baggott@stanford.edu
Phase I/II (NCT02639546)	POETIC (GO29665): A Phase I/II, Multicenter, Open-Label, Dose-Escalation Study of the Safety and Pharmacokinetics of Cobimetinib (IND# 124,530) in Pediatric and Young Adult Patients with Previously Treated Solid Tumors	POETIC	Norman Lacayo	Christina Baggott, PhD, baggott@stanford.edu
Phase I (NCT02541604)	POETIC (GO29664): An Early-Phase, Multicenter, Open-label Study of the Safety and Pharmacokinetics of Atezolizumab (MPDL3280A) In Pediatric and Young Adult Patients with Previously Treated Solid Tumors.	POETIC	Norman Lacayo	Christina Baggott, PhD, baggott@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	Prianka Kumar, RN, prianka.kumar@stanford.edu
Phase I/II (NCT02065869)	Caspacide T Cells from an HLA Partially Matched Related Donor After Negative Selection of TCR Aβ+T and B Cells in Pediatric Patients	Bellicum	Rajni Agarwal-Hashmi	Prianka Kumar, RN, prianka.kumar@stanford.edu
Phase IB (NCT01715909)	An Open-Label, Randomized, Adaptive, Two-Arm, Multicenter Trial to Evaluate Pharmacokinetics and Pharmacodynamics of Two Doses of Oseltamivir Phosphate (Tamiflu) in the Treatment of Influenza in Immunocompromised Children Younger Than 13 Years of Age with Confirmed Influenza Infection	Roche	Ami Shah	Kirstin Dougall, kirstin.dougall@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
Phase I/II (NCT02728700)	Pilot Safety and Feasibility Trial of Sirolimus and Mycophenolate for Prevention of GVHD in Mismatched Unrelated and Related Donor Hematopoietic Stem Cell Transplantation for Hematologic Malignancies	Stanford	Rajni Agarwal-Hashmi	Leigh Shinn, RN, leigh.shinn@stanford.edu
Phase I/II (Opening 5/17)	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	Leigh Shinn, RN, leigh.shinn@stanford.edu

Hematology

NCT #/Phase	Title	Sponsor	Investigator	Contact
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, emacsiray@stanford.edu
Phase II (NCT02476916)	AG348-C-003: A Phase 2, Open Label Randomized, Dose Ranging, Safety, Efficacy, Pharmacokinetic and Pharmacodynamic Study of AG-348 in Adult Patients with Pyruvate Kinase Deficiency	Agios	Bert Glader	Elaine Macasiray, RN, emacsiray@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, emacsiray@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 Naaive Severe Aplastic Anemia or Recurrent Aplastic Anemia	Novartis and Boston Children's Hospital	Bert Glader	Elaine Macasiray, RN, emacsiray@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, emacsiray@stanford.edu