

# 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 (NCT03164057)	<b>AML16: Phase II Trial of Epigenetic Priming in Patients with Newly Diagnosed Acute Myeloid Leukemia</b>	St. Jude	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT03194932)	<b>A Phase I and Expansion Cohort Study of Venetoclax in Combination with Chemotherapy in Pediatric Patients with Refractory or Relapsed Acute Myeloid Leukemia</b>	St. Jude	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02553460)	<b>TINI: Total Therapy for Infants with Acute Lymphoblastic Leukemia (ALL)</b>	St. Jude	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT01920932)	<b>HLHR13: Testing the Substitution of Brentuximab Vedotin for Vincristine in the Usual Chemotherapy and Radiation in High-Risk Pediatric Hodgkin Lymphoma</b>	St. Jude	Michael Link	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02212561)	<b>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</b>	St. Jude	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02676323)	<b>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</b>	St. Jude	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02512926)	<b>POE-14: Phase I Study of Carfilzomib in combination with Cyclophosphamide and Etoposide for Children with Relapsed or Refractory Solid Tumors and Leukemias</b>	POETIC	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02932280)	<b>POETIC-16: A Phase I/II study of Neratinib in Pediatric Patients with Relapse/Refractory Solid Tumors or Hematologic Malignancies</b>	POETIC	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02981628)	<b>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)</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT01979536)	<b>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)</b>	COG	Michael Link	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02703272)	<b>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</b>	Janssen	Michael Link	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

## Oncology: Immunotherapy

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I	<b>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</b>	Stanford	Crystal Mackall	Christin New <a href="mailto:newc@stanford.edu">newc@stanford.edu</a>
Phase I (NCT02475213)	<b>MacroGenics: A Phase 1, Open-label, Dose Escalation Study of MGA271 in Pediatric Patients with B7-H3-Expressing Relapsed or Refractory Solid Tumors</b>	Macro-Genics	Crystal Mackall	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

## Oncology: Neuro-Oncology

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II/III (NCT02114229)	<b>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</b>	St. Jude	Sonia Partap	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II/III (NCT01878617)	<b>SJMB12: A Clinical and Molecular Risk-Directed Therapy for Newly Diagnosed Medulloblastoma</b>	St. Jude	Sonia Partap	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02867592)	<b>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</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT01964300)	<b>PBTC-39: Phase II study of Peginterferon alfa-2b (SYLATRON) for pediatric patients with unresectable or recurrent craniopharyngioma</b>	PBTC	Paul Fisher	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Feasibility Study (NCT03033992)	<b>PBTC-48: Feasibility trial of Optune for children with recurrent or progressive supratentorial high-grade glioma and ependymoma</b>	PBTC	Paul Fisher	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT01089101)	<b>PBTC-029B: A Phase I and Phase II and Re-Treatment Study of AZD6244 for Recurrent or Refractory Pediatric Low Grade Glioma</b>	PBTC	Paul Fisher	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02255461)	<b>PBTC-042: Phase I study of CDK 4-6 inhibitor PD-0332991 in children with recurrent, progressive or refractory central nervous system tumors</b>	PBTC	Paul Fisher	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I/II (NCT02359565)	<b>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</b>	PBTC	Paul Fisher	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02717455)	<b>PBTC-047: Phase 1 Trial of Panobinostat in Children with Diffuse Intrinsic Pontine Glioma</b>	PBTC	Paul Fisher	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02637687)	<b>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</b>	Loxo	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02343406)	<b>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</b>	AbbVie	Sonia Partap	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

## Oncology: Solid Tumors

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I/II (NCT02932280)	<b>POETIC-16: A Phase I/II study of Neratinib in Pediatric Patients with Relapse/Refractory Solid Tumors or Hematologic Malignancies</b>	POETIC	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02512926)	<b>POE-014: Phase I Study of Carfilzomib in combination with Cyclophosphamide and Etoposide for Children with Relapsed or Refractory Solid Tumors and Leukemias</b>	POETIC	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02639546)	<b>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</b>	POETIC	Norman Lacayo	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02867592)	<b>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</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02867592)	<b>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</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase II (NCT02452554)	<b>ADVL1322: A Phase II Study of Pazopanib (GW786034, NSC# 737754) in Children, Adolescents and Young Adults with Refractory Solid Tumors</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02304458)	<b>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</b>	COG	Sheri Spunt, Crystal Mackall, Kara Davis	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02306161)	<b>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</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02470091)	<b>AOST1321: Phase II Study of Denosumab (IND# 127430, NSC# 744010), a RANK Ligand Antibody, for Recurrent or Refractory Osteosarcoma</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02484443)	<b>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</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II/III (NCT02180867)	<b>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)</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT01767194)	<b>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</b>	COG	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Cancer Genomics (NCT02868268)	<b>NANT 2015-01 New Approaches to Neuroblastoma Therapy</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase II (NCT02035137)	<b>NANT 2011-01: A Randomized Phase II Study of 131-I-MIBG vs 131-I-MIBG with Vincristine and Irinotecan vs 131-I-MIBG with Vorinostat for Resistant/Relapsed Neuroblastoma</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT01711554)	<b>NANT2011-04: A Phase I Study of Lenalidomide and Anti-GD2 Mab CH14.18 +/- Isotretinoin in Patients with Refractory/Recurrent Neuroblastoma</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02030964)	<b>NANT2012-01: A Phase I Study of Difluoromethylornithine (DFMO) and Celecoxib Cyclophosphamide/Topotecan for Patients with Relapsed or Refractory Neuroblastoma</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I (NCT02298348)	<b>NANT 2013-02: A Phase I Study of Sorafenib and Cyclophosphamide/Topotecan in Patients with Relapsed and Refractory Neuroblastoma</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02337309)	<b>NANT 2014-01: Phase I Study of SF1126 for Patients with Relapsed or Refractory Neuroblastoma</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II	<b>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</b>	NANT	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I/II (NCT02637687)	<b>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</b>	Loxo	Sheri Spunt	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>
Phase I (NCT02475213)	<b>A Phase 1, Open-Label, Dose Escalation Study of MGA271 in Pediatric Patients with B7-H3-Expressing Relapsed or Refractory Solid Tumors</b>	Macro-Genics	Crystal Mackall	Christina Baggott, PhD, <a href="mailto:baggott@stanford.edu">baggott@stanford.edu</a>

## Stem Cell Transplantation

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase I (NCT02963064)	<b>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)</b>	Stanford	Rajni Agarwal-Hashmi	Prianka Kumar, RN, <a href="mailto:prianka.kumar@stanford.edu">prianka.kumar@stanford.edu</a>
Phase I/II	<b>Use of T-allo10 cell infusions combined with mismatched related or unrelated donor hematopoietic stem cell transplantation (HSCT) for hematological malignancies</b>	Stanford	Rajni Agarwal-Hashmi	Leigh Shinn, RN, <a href="mailto:leigh.shinn@stanford.edu">leigh.shinn@stanford.edu</a>
Phase I/II (NCT02728700)	<b>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</b>	Stanford	Rajni Agarwal-Hashmi	Leigh Shinn, RN, <a href="mailto:leigh.shinn@stanford.edu">leigh.shinn@stanford.edu</a>
Phase I/II (NCT02065869)	<b>Caspacide T Cells from an HLA Partially Matched Related Donor After Negative Selection of TCR Aβ+T and B Cells in Pediatric Patients</b>	Bellicum	Rajni Agarwal-Hashmi	Prianka Kumar, RN, <a href="mailto:prianka.kumar@stanford.edu">prianka.kumar@stanford.edu</a>

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase 1B (NCT01715909)	<b>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</b>	Roche	Ami Shah	Kirstin Dougall, <a href="mailto:kirstin.dougall@stanford.edu">kirstin.dougall@stanford.edu</a>
Expanded Access (NCT02596997)	<b>An Intermediate-Size, Expanded Access Protocol to Provide Brincidofovir for the Treatment of Serious Adenovirus Infection or Disease</b>	Chimerix, Inc.	Rajni Agarwal-Hashmi	Peter Chase, <a href="mailto:peter.chase@stanford.edu">peter.chase@stanford.edu</a>

## Hematology

NCT #/Phase	Title	Sponsor	Investigator	Contact
Phase 2 (NCT02476916)	<b>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)</b>	Agios	Bert Glader	Elaine Macasiray, RN, <a href="mailto:emacsiray@stanford.edu">emacsiray@stanford.edu</a>
Phase I (NCT02303431)	<b>A Phase I, Open-Label, Single Dose, Non-Randomized Study to Evaluate Pharmacokinetics and Pharmacodynamics of Edoxaban in Pediatric Patients</b>	Daiichi Sankyo	Michael Jeng	Elaine Macasiray, RN, <a href="mailto:emacsiray@stanford.edu">emacsiray@stanford.edu</a>
Phase II (NCT02110069)	<b>SIR-DA-1202: A Randomized Phase 2 Study of Vincristine versus Sirolimus to treat High Risk Kaposiform Hemangioendothelioma (KHE)</b>	Pfizer and Boston Children's Hospital	Michael Jeng	Elaine Macasiray, RN, <a href="mailto:emacsiray@stanford.edu">emacsiray@stanford.edu</a>
Phase II (NCT030256698)	<b>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</b>	Novartis and Boston Children's Hospital	Bert Glader	Elaine Macasiray, RN, <a href="mailto:emacsiray@stanford.edu">emacsiray@stanford.edu</a>
Phase II/III (NCT02069899)	<b>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)</b>	NovImmune	Michael Jeng	Elaine Macasiray, RN, <a href="mailto:emacsiray@stanford.edu">emacsiray@stanford.edu</a>