

CENSIMENTO NEW DRUGS: CATEGORIA LEUCEMIE, LINFOMI E PATOLOGIE EMATOLOGICHE MALIGNI						
STUDIO	FARMACO	FASE	PATOLOGIE	PI/CENTRO COORDINATORE	ALTRI CENTRI PARTECIPANTI	SPONSOR
Phase 1b/2 Study of Carfilzomib in Combination with Dexamethasone, Mitoxantrone, PEG-asparaginase, and Vincristine (UK R3 Induction Backbone) in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia- CFZ008	Carfilzomib	I/II	ALL	Carmelo Rizzari Fondazione MBBM - Monza	-Ospedale Pediatrico Bambino Gesù – Roma -Presidio OIRM – Torino - Oncoematologia Pediatrica di Padova	AMGEN
Studio di fase II con nivolumab + brentuximab vedotin (N + Bv) per bambini, adolescenti e giovani adulti con linfoma di Hodgkin classico in recidiva o refrattario, CD30 +, dopo il fallimento della terapia di prima linea, seguito da brentuximab + Bendamustine (Bv + B) per i partecipanti con una risposta non ottimale	Nivolumab Brentuximab	II	Linfoma di Hodgkin	Aviano	Ospedale Gaslini – Genova; Policlinico S. Orsola- Malpighi - Bologna	Bristol-Myers Squibb
A phase I study of Inotuzumab Ozogamicin as a single agent and in combination with chemotherapy for pediatric CD22-positive relapsed/refractory Acute Lymphoblastic Leukemia	Inotuzumab Ozogamicin	I	ALL /refractory non-Hodgkin Lymphoma	Carmelo Rizzari, Fondazione MBBM Monza	-Ospedale Gaslini - Genova - Oncoematologia Pediatrica di Padova - OPBG Roma - OIRM - Torino	Erasmus Medical Center

STUDIO	FARMACO	FASE	PATOLOGIE	PI/CENTRO COORDINATORE	ALTRI CENTRI PARTECIPANTI	SPONSOR
A phase I/II study of Bosutinib in pediatric patients with Chronic Myeloid Leukemia who are resistant or intolerant to at least one prior Tyrosine Kinase Inhibitor therapy	Bosutinib	I	CML	Carmelo Rizzari, Fondazione MBBM Monza	- OPBG Roma - OIRM - Torino	Erasmus Medical Center
Open-label, single-arm trial to evaluate antitumor activity, safety and pharmacokinetics of isatuximab used in combination with chemotherapy in pediatric patients from 28 days to less than 18 years of age with relapsed/refractory B or T acute lymphoblastic leukaemia or acute myeloid leukaemia in first or second relapse	Isatuximab	II	Refractory/relapsed ALL and AML	Carmelo Rizzari, Fondazione MBBM Monza	-OPBG di Roma -IRCCS Istituto Giannina Gaslini - Genova - OIRM -Torino	Sanofi
A Phase 1/2, Multicenter, Dose-Escalating Study To Evaluate the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy Of Quizartinib Administered in Combination with Re-Induction Chemotherapy, and as a Single-Agent Maintenance Therapy, in Pediatric Relapsed/Refractory AML Subjects Aged 1 Month to <18 Years (and Young Adults Aged up to 21 Years) with FLT3-ITD mutations	Quizartinib	I/II	Relapsed/Refractory AML with FLT3-ITD mutations	Carmelo Rizzari, Fondazione MBBM Monza	- OIRM -Torino	

STUDIO	FARMACO	FASE	PATOLOGIE	PI/CENTRO COORDINATORE	ALTRI CENTRI PARTECIPANTI	SPONSOR
A Phase 1/2, Multicenter, Open-Label, Single Arm, Dose Escalation and Expansion Study of Gilteritinib (ASP2215) Combined with Chemotherapy in Children, Adolescents and Young Adults with FMS-like Tyrosine Kinase 3 (FLT3)/Internal Tandem Duplication (ITD) Positive Relapsed or Refractory Acute Myeloid Leukemia	Gilteritinib	I/II	Relapsed/ Refractory AML with FLT3-ITD mutations	Carmelo Rizzari, Fondazione MBBM Monza	- OPBG Roma - Policlinico S. Orsola, Bologna	Astellas
A Phase 1/2 Open Label Single- Arm Study of ponatinib (INCB84344) in monotherapy in pediatric participants with recurrent or refractory Leukemias or Solid Tumors	Ponatinib	I/II	Relapsed/ refractory Leukemias or Solid Tumors	Franco Locatelli OPBG Roma	-Fondazione MBBM - Monza - Ospedale Molinette - Torino - Istituto Nazionale Tumori – Milano	Daiichi Sankyo
A Pivotal Phase 1/2, Single-Arm, Open-label study to evaluate the safety and efficacy of ponatinib with chemotherapy in pediatric patients With Philadelphia Chromosome - Positive (Ph+) Acute Lymphoblastic Leukemia (ALL) who have relapsed or are resistant or intolerant to a prior tyrosine kinase inhibitor-containing	Ponatinib	I/II	Relapsed Ph+ ALL / resistant or intolerant to prior chemo+TKI Ph+ ALL /T515I positive Ph+ ALL	Leoni Veronica Fondazione MBBM Monza	-Fondazione MBBM - Monza - OPBG Roma - OIRM - Torino	Takeda

therapy, or who have the T315I mutation						
--	--	--	--	--	--	--