

ENSAYOS CLÍNICOS HEMATO-ONCOLOGÍA PEDIÁTRICA HOSPITAL UNIVERSITARIO LA PAZ

ESTUDIO	CÓDIGO/ IP	FASE	TTO EN INVESTIGACIÓN	SITUACIÓN	PROTOCOLO VIGENTE
LEUCEMIAS/ LINFOMAS					
Long Term Follow-Up of Patients Exposed to Lentiviral- Based CAR T-Cell Therapy	CCTL019A2205B IP: Berta González Novartis	Follow-up	TISAGENLECLEUCEL	Activo	Amended Protocol Version No. 03 released on 12-Jul-2019
A phase 2, single arm, multicenter, open label trial to determine the safety and efficacy of tisagenlecleucel in pediatric patients with relapsed or refractory mature B cell non-Hodgking lymphoma	CCTL019C2202 (BIANCA) IP: Berta González Novartis	2	TISAGENLECLEUCEL	Activo- ya no recluta	Clinical Trial Protocol Template Version 1.0 (01-Dec-2017). Release date: 14 Jan 2020
A Phase 1/2, Multi-Center, 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	AC220-A-U202 IP: Antonio Pérez-Martínez Daiichi Sankyo, Inc.	1/2	QUIZARTINIB	Activo	VERSION 1.0, 20 DECEMBER 2017 (Amendment 19 APR 2018)
Phase 1b/2 Study of Carfilzomib in Combination With Induction Chemotherapy in Children With Relapsed or Refractory Acute Lymphoblastic Leukemia	20140106 IP: Berta González Onyx Pharmaceuticals	1b/2	CARFILZOMIB	Activo	Amendment 9/ 04 February 2021
A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-X19 in Pediatric and Adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia or Relapsed/Refractory B-Cell Non-Hodgkin Lymphoma (ZUMA-4)	ZUMA 4 IP: Antonio Pérez Martínez EudraCT Number: 2015-005010-30	1/2	Terapia celular CAR-T	Activo	Amendment #6 13 MARCH 2020
TUMORES SÓLIDOS					
An open-label, uncontrolled, multicenter phase II trial of MK-3475 (Pembrolizumab) in Children and Young Adults with newly diagnosed Classical Hodgkin Lymphoma with inadequate (slow early) Response to Frontline Chemotherapy (KEYNOTE 667)	MK3475-667 IP: Diego Plaza Merck	2	PEMBROLIZUMAB	Activo	Protocol/Amendment No.: 667-03
A Phase 1/2 single-arm study evaluating the safety and efficacy of eribulin mesilate in	E7389-G000-213	1/2	ERIBULINA	Cerrado en	Amendment 01

Actualizado: abril 2021

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combination with irinotecan in children with refractory or recurrent solid tumors	IP: Ana Sastre Eisai			Sept 2021	10 May 2018
A Phase I, Open-label, Parallel Group Study to Investigate Olaparib Safety and Tolerability, Efficacy and Pharmacokinetics in Paediatric Patients (aged 6 months to 17 years) with Solid Tumour	D0816C00025 (LYNPARZA) IP: Pedro Rubio Astra Zeneca	1	OLAPARIB	Activo	3.0 18 May 2020
A Multicenter, Open-label, Randomized Phase 2 Study to Compare the Efficacy and Safety of Lenvatinib in Combination with Ifosfamide and Etoposide versus Ifosfamide and Etoposide in Children, Adolescents and Young Adults with Relapsed or Refractory Osteosarcoma (OLIE)	E7080-G000-230 IP: Ana Sastre Eisai	2	LENVATINIB	Activo	FINAL: 08 Oct 2019
CAMPFIRE: A Study of Ramucirumab (LY3009806) in Children and Young Adults With Desmoplastic Small Round Cell Tumor (JS1-MC-JV01)	NCT04145349 IP: Pedro Rubio Eli Lilly	1/2	Ramucirumab	Activo	Protocol Addendum Amendment JV01(d)
CAMPFIRE: A Study of Ramucirumab (LY3009806) in Children and Young Adults With Synovial Sarcoma	NCT04145700 IP: Pedro Rubio Eli Lilly	1/2	Ramucirumab	Activo	Protocol Addendum Amendment JV02(f)
A PHASE 1, MULTICENTRE, OPEN-LABEL, DOSE-ESCALATION AND COHORT EXPANSION STUDY OF NIRAPARIB AND DOSTARLIMAB IN PAEDIATRIC PATIENTS WITH RECURRENT OR REFRACTORY SOLID TUMOURS	EudraCT Number: 2020- 002359-39 IP: Pilar Guerra GSK	1	Niraparib Dostarlimab	Activo	1.1 (version 1.0 never implemented)
Tumor-agnostic precision immuno-oncology and somatic targeting rational for you (tapistry) phase ii platform trial (TAPISTRY)	IP: Javier de Castro	2		Activo	
TPH					
A Phase I/II open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric patients with grade II-IV acute graft vs. host disease after allogeneic hematopoietic stem cell transplantation	CINC424F12201 (REACH 4) IP: Yasmina Mozo	1/2	RUXOLITINIB	Activo- ya no recluta	01-Apr-2019
A phase 2 open-label, single-arm, multi-center study of ruxolitinib added to corticosteroids in pediatric subjects with moderate and severe chronic graft vs. Host disease after allogeneic stem cell transplantation	CINC424G12201 (REACH 5) IP: Yasmina Mozo	2	RUXOLITINIB	Activo	08-Apr-2019

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<p>A Phase 2b open-label, single-arm study to evaluate pharmacokinetics, efficacy, safety and tolerability of letermovir in pediatric participants from birth to less than 18 years of age at risk of developing CMV infection and/or disease following allogeneic haematopoietic stem cell transplantation (HSCT)</p>	<p>MK8228-030 IP: Antonio Perez-Martínez Merck</p>	<p>2b</p>	<p>LETERMOVIR</p>	<p>Activo</p>	<p>030-00</p>
<p>Phase 1/2 Dose Finding, Safety and Efficacy Study of Ibrutinib in Pediatric Subjects with Chronic Graft Versus Host Disease (cGVHD)</p>	<p>PCYC-1146-IM IP: Luisa Sisinni</p>	<p>1/2</p>	<p>IBRUTINIB</p>	<p>Activo</p>	<p>17 September 2018</p>
<p>A Phase 3, Open-label, Single Arm, Multicenter Study of Ravulizumab in Addition to Best Supportive Care in Pediatric Participants (from 1 month to < 18 years of age) with Thrombotic Microangiopathy (TMA) after Hematopoietic Stem Cell Transplantation (HSCT): ALXN1210-TMA-314</p>	<p>EudraCT number: 2020-000761-16 IP: David Bueno Alexion Pharmaceuticals, Inc.</p>	<p>3</p>	<p>Ravulizumab</p>	<p>Activo</p>	<p>25 Mar 2020</p>