

Nr. crt.	Cod protocol	Numar EudraCT	Medicament de investigatie clinica testat	Medicament de investigatie clinica comparator	Placebo	Aria terapeutică	Sponsor	International / national	Denumirea studiului (s-a pastrat denumirea originala - in limba engleza)	Faza	Nr. estimat de pacienti pentru Romania	Data autorizarii studiului clinic de catre ANMDM	Data opiniei CNBMDM	Data inceperii studiului	Inchidere studiu la nivel global/ Romania	Inchidere temporara
1	ARGX-113-1701	2017-002333-40	ARGX-113	Nu	Nu	Afectiuni ale pielii și țesutului conjunctiv	argenx BVBA, Belgia	unicentric	An Open-label, Non-controlled, Phase II Study to Evaluate the Safety, Pharmacodynamics, Pharmacokinetics, Efficacy and Conditions of Use of ARGX-113 in Patients with Mild to Moderate Pemphigus Vulgaris	II	27	4/11/2019				
2	CAIN457K2340	2017-000679-10	Cosentyx® (secukinumab, AIN457)	Adalimumab	Da	Afectiuni ale sistemului musculo-scheletic	Novartis Pharma AG, Elveția	multicentric	A randomized, partially-blinded, active-controlled multicenter study of secukinumab to demonstrate reduction of radiographic progression versus GP2017 (adalimumab biosimilar) at 104 weeks and to assess the long term safety, tolerability and efficacy up to 2 years in patients with active ankylosing spondylitis	III	24	4/1/2019	3/6/2018			
3	BIA-2093-211	2012-001091-11	Eslicarbazepine acetate (BIA 2-093)	Nu	Nu	Afectiuni ale sistemului nervos	BIAL - Portela & Ca, S.A., Portugalia	multicentric	Open-label, 2-dose level trial to evaluate pharmacokinetics, safety, and tolerability of eslicarbazepine acetate (ESL) as adjunctive therapy in infants with refractory epilepsy with partial-onset seizures aged from 1 month to <2 years	II	10	4/5/2019	7/4/2017			
4	BIA-2093-211/EXT	2016-001072-29	Eslicarbazepine acetate (BIA 2-093)	Nu	Nu	Afectiuni ale sistemului nervos	BIAL - Portela & Ca, S.A., Portugalia	multicentric	Open-label, 2-dose level trial to evaluate pharmacokinetics, safety, and tolerability of eslicarbazepine acetate (ESL) as adjunctive therapy in infants with refractory epilepsy with partial-onset seizures aged from 1 month to <2 years – 1-year extension	II	10	4/5/2019	7/4/2017			
5	MK-6072-001	2017-000070-11	Bezlotoxumab (Zinplava™) MK-6072	Nu	Da	Afectiuni ale sistemului digestiv	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., SUA	multicentric	A Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of a Single Infusion of Bezlotoxumab (MK 6072, Human Monoclonal Antibody to C. difficile Toxin B) in Children Aged 1 to <18 Years Receiving Antibacterial Drug Treatment for C. difficile Infection (MODIFY III)	III	12	4/25/2019				
6	POL7080-011 INCHIS TEMPORAR	2017-003933-27	Murepavadin combined with one anti-pseudomonal antibiotic	Two anti-pseudomonal antibiotics	Nu	Afectiuni ale tractului respirator	Polyphor Ltd., Elveția	multicentric	A multicenter, open-label, randomized, active-controlled, parallel group, pivotal study to investigate the efficacy, safety and tolerability, and pharmacokinetics of murepavadin combined with one anti-pseudomonal antibiotic versus two anti-pseudomonal antibiotics in adult subjects with ventilator-associated bacterial pneumonia suspected or confirmed to be due to Pseudomonas aeruginosa	III	16	4/19/2019	5/24/2018			
7	GC-627-05	2016-003553-15	Neulasta	Nu	Nu	Afectiuni oncologice	Generon (Shanghai) Corporation Ltd., China	multicentric	A Phase III, Randomized, Multi-Centre, Open-Label, Fixed Dose, Neulasta Active-Controlled Clinical Trial of F-627 in Women with Breast Cancer Receiving Myelotoxic Chemotherapy	III	33	4/11/2019	6/7/2018			
8	RPC01-3203	2017-004294-14	Ozanimod	Nu	Da	Afectiuni ale sistemului digestiv	Celgene International II Sàrl, Elveția	multicentric	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of Oral Ozanimod as Maintenance Therapy for Moderately to Severely Active Crohn's Disease	III	13	4/11/2019				
9	RPC01-3204	2017-004295-55	Ozanimod	Nu	Nu	Afectiuni ale sistemului digestiv	Celgene International II Sàrl, Elveția	multicentric	A Phase 3, Multicenter, Open-Label Extension Study of Oral Ozanimod for Moderately to Severely Active Crohn's Disease	III	13	4/11/2019				
10	20180015	2018-000665-36	Carfilzomib in combinatie cu Lenalidomide si Dexamethason e	Nu	Nu	Afectiuni oncologice	Amgen Inc., SUA	unicentric	A Randomized, Open-label, Phase 3 Study Comparing Once-weekly vs Twice-weekly Carfilzomib in Combination with Lenalidomide and Dexamethasone in Subjects With Relapsed or Refractory Multiple Myeloma (A.R.R.O.W.2)	III	63	4/25/2019	3/28/2019			

11	<b>I4V-MC-JAIM</b>	2017-005028-11	Baricitinib	Nu	Da	Afecțiuni ale sistemului imunitar	Eli Lilly and Company, SUA	multicentric	A Phase 3, Double-Blind, Multicenter Study to Evaluate the Long-Term Safety and Efficacy of Baricitinib in Patients with Systemic Lupus Erythematosus (SLE)	III	68	<b>4/11/2019</b>				
12	<b>EFC15804</b>	2018-001953-28	Dupilumab	Nu	Da	Afecțiuni ale tractului respirator	Sanofi-aventis Recherche & Développement, France	multicentric	A Randomized, Double-blind, Placebo-controlled, Parallel-group, 52-week Pivotal Study to Assess the Efficacy, Safety, and Tolerability of Dupilumab in Patients with Moderate-to-severe Chronic Obstructive Pulmonary Disease (COPD) with Type 2 inflammation	III	23	<b>4/24/2019</b>				