

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
1	AB11003 Respins	2012-004222-25	Masitinib mesylate (AB1010)	NU	DA	Afecțiuni ale sistemului digestiv	AB Science	multicentric	A 12-week with possible extension, prospective, multicenter, randomised, double-blind, controlled, 2-parallel groups, phase 2b/3 study to compare efficacy and safety of masitinib to placebo, in the treatment of moderate Crohn's disease in patients intolerant or with unsatisfactory response to immunosuppressive drugs and/or TNF-inhibitors	II/III	30	9/30/2019			
2	AB14005, Respins	2015-000897-36	Masitinib mesylate (AB1010)	NU	DA	Afecțiuni oncologice	AB Science	multicentric	A prospective, multicentre, double-blind, randomized, placebo-controlled, phase 3 study to evaluate efficacy and safety of masitinib with irinotecan in patients with advanced-stage esophagogastric adenocarcinoma who have relapsed after first-line chemotherapy	III	50	9/30/2019			
3	CA224-047	2017-003583-12	Relatlimab	Nivolumab	NU	Afecțiuni oncologice	Bristol-Myers Squibb International Corporation, Belgium	multicentric	A Randomized, Double-Blind Phase 2/3 Study of Relatlimab Combined with Nivolumab versus Nivolumab in Participants with Previously Untreated Metastatic or Unresectable Melanoma	II/III	50	9/30/2019	10/17/2018		
4	331-10-234	2017-001447-12	Brexipiprazole (OPC-34712)	Aripiprazol	DA	Afecțiuni psihice	Otsuka Pharmaceutical Development & Commercialization, Inc., SUA	multicentric	A Multicenter, Randomized, Double-blind, Placebo- and Active controlled Trial to Evaluate the Efficacy of Brexpiprazole Monotherapy for the Treatment in Adolescents (13-17 years old) With Schizophrenia	III	20	9/30/2019			
5	331-10-236	2017-001459-30	Brexipiprazole (OPC-34712)	NU	NU	Afecțiuni psihice	Otsuka Pharmaceutical Development & Commercialization, Inc., SUA	multicentric	A Long-term, Multicenter, Open-label Trial to Evaluate the Safety and Tolerability of Flexible-Dose Brexpiprazole as Maintenance Treatment in Adolescents (13-17 Years Old) With Schizophrenia	III	20	9/30/2019			
6	CA045-001	2018-001423-40	NKTR-214 + Nivolumab	Nivolumab	NU	Afecțiuni oncologice	Bristol-Myers Squibb International Corporation, Belgium	multicentric	A Phase 3, Randomized, Open-label Study of NKTR-214 Combined with Nivolumab Versus Nivolumab in Participants with Previously Untreated Unresectable or Metastatic Melanoma	III	37	9/30/2019			
7	CHF201701 Respins	2018-000486-37				Afecțiuni cardio-vasculare	Heart Initiative, SUA	multicentric	Safety, Tolerability and efficacy of Rapid Optimization, helped by NT-proBNP and GDF-15, of Heart Failure therapies (STRONG-HF)	IV	150	9/25/2019			
8	BOS161721-02	2018-000305-23	BOS161721	NU	DA	Afecțiuni reumatologice	Boston Pharmaceuticals, Inc., SUA	multicentric	A Randomized Double-Blind Phase 1b/2 Combined Staggered Multiple Dose Escalation Study of BOS161721 in Systemic Lupus Erythematosus (SLE) Patients on a Background of Limited Standard of Care	II	8	9/30/2019	4/25/2019		
9	EP0092	2018-002303-33	Padsevonil	NU	DA	Afecțiuni neurologice	UCB Biopharma SPRL, Belgium	multicentric	A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of Padsevonil as Adjunctive Treatment of Focal-Onset Seizures in Adult Subjects With Drug-Resistant Epilepsy	III	35	9/30/2019			
10	CRN00808-03	2018-002230-20	CRN00808	NU	DA	Afecțiuni endocrinologice	Crinetics Pharmaceuticals, Inc., SUA	multicentric	An open label exploratory study to evaluate the safety, pharmacokinetics and efficacy of CRN00808 in patients with acromegaly treated with somatostatin analogue based treatment regimens (ACROBAT EDGE)	II	10	9/30/2019			
11	CRN00808-02	2018-001833-42	CRN00808	NU	DA	Afecțiuni endocrinologice	Crinetics Pharmaceuticals, Inc., SUA	multicentric	A double-blind, placebo-controlled, randomized withdrawal study to evaluate the safety, pharmacokinetics and efficacy of CRN00808 in patients with acromegaly that are responders to octreotide LAR or lanreotide depot (ACROBAT EVOLVE)	II	10	9/30/2019			

12	DCR-PHXC-201	2018-003098-91	DCR-PHXC	NU	DA	Afectiuni nefrologice	Dicerna Pharmaceuticals Inc., SUA	multicentric	A Phase 2 Placebo-Controlled, Double-Blind, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of DCR-PHXC Solution for Injection (subcutaneous use) in Patients with Primary Hyperoxaluria	II	6	9/30/2019	5/6/2019		
13	DCR-PHXC-301	2018-003099-10	DCR-PHXC	NU	NU	Afectiuni nefrologice	Dicerna Pharmaceuticals Inc., SUA	multicentric	An Open-Label Roll-Over Study to Evaluate the Long-Term Safety and Efficacy of DCR PHXC Solution for Injection (subcutaneous use) in Patients with Primary Hyperoxaluria	III	10	9/30/2019			
14	MK-7655A-016-01	2018-003202-82	Imipenem/Cilastatin/Relebactam (MK-7655A)	Piperacillin/Tazobactam	NU	Infectii bacteriene si micotice	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., SUA	multicentric	A Multi-national Phase 3, Randomized, Double-Blind, Active Comparator-Controlled Clinical Trial to Study the Safety, Tolerability, and Efficacy of Imipenem/Cilastatin/Relebactam (MK-7655A) Versus Piperacillin/Tazobactam in Subjects with Hospital-Acquired Bacterial Pneumonia or Ventilator-Associated Bacterial Pneumonia	III	8	9/30/2019	6/19/2019		
15	C-935788-057 VHP1434 (VHP2019013) Respins	2018-004774-97	Fostamatinib Disodium R935788	NU	DA	Afectiuni hematologice autoimune	Rigel Pharmaceuticals, Inc., SUA	multicentric	A Phase 3, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Study of Fostamatinib Disodium in the Treatment of Warm Antibody Autoimmune Hemolytic Anemia	III	9	9/25/2019			
16	I4V-MC-JAJA VHP1479 (VHP2019054)	2018-003351-37	Olumiant (Baricitinib) LY3009104	Enbrel sau Humira	NU	Afectiuni musculo-scheletice	Eli Lilly and Company, SUA	multicentric	A Randomized, Active Controlled, Parallel Group, Phase 3b/4 Study of Baricitinib in Patients with Rheumatoid Arthritis	III/IV	60	9/25/2019			