

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	ISIS766720-CS2	2017-004259-22	ISIS766720	NU	DA	Afectiuni ale sistemului musculo-scheletic	Ionis Pharmaceuticals, Inc., USA	multicentric	A Double Blind, Placebo-Controlled, Phase 2 Study to assess the Safety, Tolerability and Efficacy of ISIS 766720 (IONIS GHR-LRX, an Antisense Inhibitor of the Growth Hormone Receptor) Administered Once Every 28 Days for 16 Weeks in Patients with Acromegaly Being Treated with Long-acting Somatostatin Receptor Ligands (SRL)	II	11	6/11/2019	11/26/2018		
2	C3601009	2017-004544-38	ATM-AVI	NU	NU	Infectii bacteriene și micoze	Pfizer Inc., NY, USA	multicentric	A prospective, randomized, open-label, comparative study to assess the efficacy, safety and tolerability of aztreonam/avibactam (ATM-AVI) and best available therapy for the treatment of serious infections due to multi-drug resistant gram-negative bacteria producing metallo-beta-lactamase (MBL).	III	3	6/10/2019			
3	MK-3475-630	2018-001974-76	Pembrolizumab	NU	DA	Afectiuni oncologice	MSD, a subsidiary of Merck&Co., Inc., USA	multicentric	A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate Pembrolizumab Versus Placebo as Adjuvant Therapy Following Surgery and Radiation in Participants with High-risk Locally Advanced Cutaneous Squamous Cell Carcinoma (LA cSCC) (KEYNOTE-630)	III	32	6/18/2019	4/8/2019		
4	MK-7339-002	2018-003007-19	Olaparib	NU	NU	Afectiuni oncologice	MSD, a subsidiary of Merck&Co., Inc., USA	multicentric	A Phase 2 Study of Olaparib Monotherapy in Participants with Previously treated, Homologous Recombination Deficiency (HRD) Positive Advanced Cancer	II	18	6/28/2019	3/4/2019		
5	P2-IMU-838-MS	2018-001896-19	IMU-838	NU	DA	Afectiuni ale sistemului nervos	Immunic AG, Germany	multicentric	Randomized, double-blind, placebo-controlled, multicenter Phase 2 trial assessing the effect of IMU-838 on disease activity, as measured by magnetic resonance imaging (MRI), as well as safety and tolerability in patients with relapsing-remitting multiple sclerosis (RRMS)	II	40	6/21/2019			
6	JBT101-CF-002	2017-003723-29	Lenabasum	NU	DA	Afectiuni ale tractului respirator	Corbus Pharmaceuticals, Inc., USA	multicentric	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2 Trial to evaluate Efficacy and Safety of Lenabasum in Cystic Fibrosis	II	10	6/18/2019			
7	ECRI-12-001	2012-003515-58	Ticagrelor + Aspirin	Current day intensive dual antiplatelet	NU	Afectiuni cardiovasculare	ECRI, Netherlands	multicentric	Comparative effectiveness of 1 month of ticagrelor plus aspirin followed by ticagrelor monotherapy versus a current day intensive dual antiplatelet therapy in all comers patients undergoing percutaneous coronary intervention with bivalirudin and BioMatrix family Drug-Eluting Stent use.	III	1200	Respins			
8	001CTFiterman	2014-003188-39	Sindolor gel	NU	NU	Terapia durerii	Fiterman Pharma	multicentric	Eficacitatea Sindolor gel ca analgezic local In procedura de litotritie extracorporeala*	III	300	Respins			
9	TV50717-CNS-30060	2017-002976-24	Deutetrabenazine	NU	DA	Afectiuni ale sistemului nervos	Teva Branded Pharmaceutical Products R&D, Inc., USA	multicentric	A Well-Controlled, Fixed-Dose Study of TEV 50717 (Deutetrabenazine) for the Treatment of Tics Associated with Tourette Syndrome	III	11	6/28/2019	7/25/2018		
10	TV50717-CBS-30047	2016-000630-22	Deutetrabenazine (TEV-50717)	NU	DA	Afectiuni ale sistemului nervos	Teva Branded Pharmaceutical Products R&D, Inc., USA	multicentric	An Open-Label, Long-Term Safety Study Including a Double-Blind, Placebo-Controlled, Randomized Withdrawal Period of TEV-50717 (deutetrabenazine) for the Treatment of Tourette Syndrome in Children and Adolescents	III	9	6/28/2019	7/25/2018		
11	SHP647-304	2017-000574-11	SHP647	NU	NU	Afectiuni ale sistemului digestiv	Shire Human Genetic Therapies, Inc, USA	multicentric	A Phase 3 Long-term Safety Extension Study of SHP647 in Subjects with Moderate to Severe Ulcerative Colitis or Crohn's Disease (AIDA)	III	22	28.06.2019.			
12	SHP647-305	2017-000575-88	SHP647	NU	DA	Afectiuni ale sistemului digestiv	Shire Human Genetic Therapies, Inc, USA	multicentric	A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Efficacy and Safety Study of SHP647 as Induction Therapy in Subjects With Moderate to Severe Crohn's Disease (CARMEN CD 305)	III	35	6/28/2019			
13	SHP647-307	2017-000617-23	SHP647	NU	DA	Afectiuni ale sistemului digestiv	Shire Human Genetic Therapies, Inc, USA	multicentric	A Phase 3 Randomized, Double-blind, Placebo-controlled, Parallel-group Efficacy and Safety Study of SHP647 as Maintenance Therapy in Subjects With Moderate to Severe Crohn's Disease (CARMEN CD 307)	III	35	6/28/2019			
14	EFC15156	2017-003510-16	Sotagliflozin	NU	DA	Afectiuni cardiovasculare	Sanofi-aventis Recherche & Développement, France	multicentric	A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Effects of Sotagliflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes POST Worsening Heart Failure	III	160	6/28/2019	11/29/2018		
15	I6T-MC-AMBG	2017-003238-96	LY3074828	NU	DA	Afectiuni ale sistemului digestiv	Eli Lilly and Company, USA	multicentric	A phase 3, multicenter, randomized, double-blind, parallel-arm, placebo-controlled maintenance study of mirikizumab in patients with moderately to severely active ulcerative colitis (Lucent 2).	III	10	6/28/2019			
16	I6T-MC-AMAN	2017-003229-14	Mirikizumab	NU	DA	Afectiuni ale sistemului digestiv	Eli Lilly and Company, USA	multicentric	A Phase 3, Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Induction Study of Mirikizumab in Conventional-Failed and Biologic-Failed Patients with Moderately to Severely Active Ulcerative Colitis (LUCENT 1)	III	11	6/28/2019			
17	CACZ885T2301	2017-004011-39	Canakinumab	NU	DA	Afectiuni oncologice	Novartis Pharma AG, Switzerland	multicentric	A phase III, multicenter, randomized, double blind, placebo-controlled study evaluating the efficacy and safety of canakinumab versus placebo as adjuvant therapy in adult subjects with stages AJCC/UICC v. 8 II-IIIa and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC)	III	25	6/28/2019	9/24/2018		
18	B3461058		NA	NA	NA	Afectiuni cardiovasculare	ZEINCRO U.K Ltd.	multicentric	Prevalence and characteristics of transthyretin amyloidosis in patients with left ventricular hypertrophy of unknown etiology	IV non-interventional	200	6/28/2019			
19	COSMOS P16-831		Levodopa / carbidopa gel	NA	NA	Afectiuni ale sistemului nervos	Abbvie GmbH, Germania	multicentric	COSMOS P16-831 – studiu de co-medicatie de evaluare a tratamentului cu levodopa-carbidopa gel intestinal in monoterapie sau in terapie combinata	IV non-interventional	160	6/28/2019			