Clinical Trials Registry at EDA

SN	Study Code (Specified as per the submitted protocol)	Study title	Study type: -Interventional -Observational	Study Phase (I, II, III, or IV)	Sites "At which the clinical trials will be conducted in Egypt"	Status: -Approved -Ongoing -Suspended -Terminated -Completed -Withdrawal	Conditions / Therapeutic area	Interventions "Used IMPs & its type (Biological, Pharmaceutical, Innovative, Herbal, or medical device)
1	M15-991	A multi-center, randomized, double-blind, placebo-controlled induction study to assess the efficacy and safety of Risankizumab in subjects with moderately to severely active Crohn's disease who failed prior biologic treatment	Interventional	III	1-CRC, Alexandria university 2-CRC, Alexandria university 3-Faculty of medicine, Cairo university 4- MASRI-CRC, Ain Shams University 5-NHTMRI 6-Faculty of medicine, Zagazig university	Approved 26/3/2019 Completed 3/11/2021	moderately to severely active Crohn's disease who failed prior biologic treatment	(Biological) Risankizumab
2	M16-000	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Crohn's Disease who respond to induction treatment in M16-006 or	Interventional	III	Two sites at Faculty of Medicine, CRC, Alexandria University	Approved 26/3/2019 Ongoing	Crohn's disease	(Biological) Risankizumab

		M15-991 ; or completed M15-989						
3	M16-066	A Multicenter, Randomized, Double-Blind, Placebo-Controlled 52-Week Maintenance and an Open-Label Extension Study of the Efficacy and Safety of Risankizumab in Subjects with Ulcerative Colitis	Interventional	III	1-Fcaulty of medicine, Alexandria University 2-CRC, Alexandria University 3-Air Force Specialized Hospital Research 4- National Liver Institute, Menoufia University	Approved 10/6/2019 Ongoing	Ulcerative Colitis	(Biological) Risankizumab
4	M16-067	Multicenter randomized double-blind placebo-controlled induction study to evaluate the efficacy and safety of Risankizumab in subjects with moderately to severely active ulcerative colitis.	Interventional	III	1- CRC, Alexandria University 2-National Liver Institute, Menoufia University 3-Air Force Specialized Hospital 4-Faculty of Medicine, Alexandria University	Approved 10/6/2019 Ongoing	Active ulcerative colitis.	(Biological) Risankizumab
5	QGE031	A Multicenter, Randomized, double-blind active and placebo-controlled study to investigate the efficacy and safety of Ligelizumab in the treatment of chronic spontaneous urticaria in adolescents and adults in	Interventional	III	1-Faculty of medicine, Alexandria university 2-Faculty of medicine, Ain Shams University	Withdrawn 31/8/2020	Chronic spontaneous Urticaria	(Biological) Ligelizumab

		adequately controlled with H1 antihistamines						
6	ARTEMIS -DM "LPS15396"	A multicenter, multinational, prospective, interventional, single-arm, Phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin	Interventional	IV	1-Faculty of medicine, Alexandria university 2-CRC, Alexandria university 3-GOTHI 4-Faculty of medicine, Menoufia university 5-Faculty of medicine, Ain Shams univeristy	Approved 9/2/2020 Withdrawn	Type 2 diabetes mellitus	(Biological) Insulin glargine "Toujeo"
7	STEAD FAST	A phase II, multicenter, randomized, open label, two arm study comparing the effect of crizanlizumab+ SOC alone on renal function in sickle cell disease patients ≥16 years with chronic kidney disease due to sickle cell nephropathy	Interventional	II	Abu El Resh Children Hospital	Approved 5/5/2020 Withdrawn 3/8/2021	Sickle cell anemia	(Biological) Crizanlizumab
8	STAND	A Phase III, multicenter, double-blind study to assess efficacy and safety of two doses of crizanlizumab vs placebo with or without hydroxyurea / hydroxycarbamide therapy, in adolescent and adult sickle	Interventional	III	1-Faculty of medicine, Alexandria university 2-Faculty of medicine, Ain Shams university	Approved 20/2/2020 Withdrawn 3/8/2021	Sickle cell anemia	(Biological) Crizanlizumab

		cell disease patients with vaso-occlusive crisis						
9	WA40404	A Phase III b Multicenter, Randomized, double-blind, Placebo-controlled study to evaluate the efficacy and safety of Ocrelizumab in adults with primary progressive Multiple Sclerosis	Interventional	IIIb	1-Sayed Galal Hospital 2-Faculty of medicine, Alexandria university 3-CRC, MASRI, Ain Shams University	Approved 23/8/2020 Withdrawn 25/8/2021	Primary progressive multiple sclerosis	(Biological) Ocrelizumab
10	1368-0025	Open label long term extension study to assess the safety and efficacy of BI655130 treatment in patients with generalized pustular psoriasis	Interventional	IIb	Alexandria university hospital/ Dermatology department	Approved 18/5/2021 Withdrawn 31/10/2021	Generalized pustular psoriasis	(Biological) Spesolimab
11	05-Gam-COVID-Vac-2020	A Phase III, randomized, double blind, placebo-controlled trial to evaluate immunogenicity and safety of the Gam-COVID-Vac combined vector vaccine in prophylactic treatment for SARS-COV-2 infection in Egypt	Interventional	III	1-National liver institute, Menoufia university 2-CRC, Alexandria university 3- CRC, MASRI, Ain Shams University	Withdrawn 12/6/2022	COVID-19 prophylaxis	(Biological) Russian Gam-COVID-Vac Combine vector vaccine
12	CNBG2020003SQ	Multicenter, Randomized, Double blind, parallel placebo controlled, Phase III clinical trial to evaluate the protective efficacy, safety and immunogenicity of	Interventional	III	1-Vacsera Health care facility 2-Ktameya medical center	Approved 28/3/2022 Completed 31/7/2022	COVID-19 Prophylaxis	(Biological) Inactivated SARS-COV-1 Vaccine

		Inactivated SARS-COV-2 Vaccines in healthy population aged 18 years old and above						
13	D910DC00001 (Emerald-2)	A phase 3 randomized double blind placebo controlled multicentre study of durvalumab monotherapy or in combination with bevacizumab as adjuvant therapy in patients with hepatocellular carcinoma who are at high risk of recurrence after curative hepatic resection or ablation	Interventional	III	1-Alexandria University-CRC 2-National Liver Institute-Menoufia University 3-National Hepatology & Tropical Medicine Research Institute 4-Air Force specialized Hospital 5-Assuit University	Approved 12/12/2021 Ongoing	Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation	(Biological) Durvalumab\ Bevacizumab
14	01-Sputnik-Light-2021	A phase III, randomized, double-blind, placebo-controlled international multi-site clinical trial in parallel assignment to evaluate efficacy, immunogenicity and safety of the Sputnik Light vector vaccine in adults in the SARS-Cov-2 infection prophylactic treatment	Interventional	III	1- National hepatology and tropical medicine center 2-Katemeya medical center	Approved 24/8/2021 Completion of study visit 31/8/2022	COVID-19 Prophylaxis	(Biological) Sputnik Light vector vaccine
15	KATE-3	A randomized, multi-center, double blind, placebo-controlled phase III study of	Interventional	III	1-Kasr Al Ainy hospital 2-Shefaa Al orman hospital	Approved 5/12/2021	HER2-positive and PD-L1-	(Biological)

		the efficacy and safety of Trastuzumab Emtansine in combination with Atezolizumab or placebo in Pts with HER2-positive and PD-L1- positive locally advanced or metastatic breast cancer who have received prior Trastuzumab + Atezolizumab and Taxane-based therapy			3-Baheya hopsital	Withdrawn 19/12/2022	positive locally advanced or metastatic breast cancer	Trastuzumab Emtansine/ Atezolizumab
16	CAIN457P 12301	A randomized, double blind, placebo-controlled, parallel group, phase III multi-center study of intravenous Secukinumab to compare efficacy at 16 weeks with placebo and to assess safety and tolerability up to 52 weeks in subjects with active ankylosis spondylitis of non-radiographic axial spondylo arthritis	Interventional	III	Clinical research center, Alexandrian university	Withdrawn 3/11/2021	Active ankylosis spondylitis	(Biological) Secukinumab
17	TG2101V0 1	A Global, Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the Efficacy, Safety and Immunogenicity of Recombinant SARS-CoV-2	Interventional	III	National Hepatology and Tropical Medicine Research institute	Withdrawn 16/1/2022	COVID-19 Prophylaxis	(Biological) Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01)

		Fusion Protein Vaccine (V-01) in Adults Aged 18 Years and Older",						
18	MO42541 IMPRAVE	A phase III, open label, randomized study of Atezolizumab with Lenvatinib or Sorafenib versus Lenvatinib or sorafenib alone in hepatocellular carcinoma previously treated with Atezolizumab and Bevacizumab	Interventional	III	Air force specialized hospital	Approved 2/2/2022	Hepatocellular carcinoma	(Biological) Atezolizumab/ Lenvatinib/ Sorafenib
19	COVID_VACC_1	A Phase 1 Clinical Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Inactivated SARS-CoV-2 Vaccine Against COVID-19 in Healthy Adults	Interventional	I	National research center	Approved 9/11/2021 Suspended 9/12/2021	Covid-19 Prophylaxis	(Biological) Inactivated SARS-CoV-2 Vaccine
20	SPHINX-EGYPT SPHINX22 122020	Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS-CoV-2 Infection (COVID-19)	Interventional	I	Al-Manial specialized university Hospital	Approved 3/2/2022 Database lock 26/9/2023	Covid-19 Prophylaxis	(Biological) EgyVax
21	GBT2104-131	A randomized double blinded placebo controlled multicentre study to access the safety and efficacy of Inclacumab in participants with sickle cell	Interventional	III	1-Faculty of medicine, Mansoura University 2-Faculty of medicine, Zagazig University	Approved 14/6/2022	sickle cell disease patients with Vaso-	(Biological) Inclacumab

		disease experiencing Vaso-occlusive crisis			3-MASRI-CRC,Ain Shams University 4-CRC,Alexandria University 5- Alexandria University, Hematology department 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.	Ongoing	occlusive crisis	
22	GBT2104-132	A Randomized, Double-blind, Placebo-controlled, Multicenter Study of a Single Dose of Inclacumab to Reduce Re-admission in Participants with Sickle Cell Disease and Recurrent Vaso-occlusive Crises (GBT-132)	Interventional	III	1. Faculty of medicine, Mansoura University 2. Faculty of medicine, Zagazig University 3. MASRI, CRC, Ain Shams University 4.CRC, Alexandria University 5- Alexandria University, Hematology department 6. Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.	Approved 14/6/2022 Withdrawn 29/6/2023	Sickle cell disease patients with Vaso-occlusive crisis	(Biological) Inclacumab
23	GBT2104-133	An Open-label Extension Study to Evaluate the Long-term Safety of Inclacumab Administered to Participants	Interventional	III	1-Faculty of medicine, Mansoura University 2- Faculty of medicine, Zagazig University	Approved 14/6/2022	sickle cell disease	(Biological) Inclacumab/

		with Sickle Cell Disease Who Have Participated in an Inclacumab Clinical Trial			3- CRC, MASRI, Ain Shams University 4-CRC,Alexandria University 5- Alexandria University, Hematology department 6- Cairo University, Abo El-Resh Hospital 7- CRC, Cairo University 8- Cairo University, Hematology department.			Placebo
24	Consonance-MN39159	An open-label, single-arm 4-year study to evaluate effectiveness and safety of ocrelizumab treatment in patients with progressive multiple sclerosis	Interventional	III	1-Faculty of Medicine, Alexandria university, CRC 2-MASRI, Ain Shams university, CRC	Approved 20/9/2022 Ongoing	Progressive multiple sclerosis	(Biological) Ocrelizumab
25	20200404 (IMBCAM)	A randomized double-blinded placebo-controlled Phase III clinical trial of SARS-COV-2 vaccine inactivated (Vero cell) in adult aged 18 years and above	Interventional	III	1-Katemeya Medical Center 2-Tropical Medicine Department, National Hepatology	Withdrawn 24/2/2022	Covid-19 Prophylaxis	(Biological) Inactivated SARS-COV-2 vaccine
26	TRISTARDS-0135-0347	The TRISTARDS trial - ThRombolys is Therapy for ARDS A Phase IIb/III operationally seamless, open-label, randomized, sequential, parallel-group adaptive study to evaluate the efficacy	Interventional	IIb/III	1.National Hepatology and Tropical Medicine Research Institute 2.Abbasia Fever Hospital 3.Imbaba Fever Hospital	Withdrawn 20/7/2022	Respiratory distress syndrome (ARDS) triggered by COVID-19	(Biological) Alteplase

		and safety of daily intravenous alteplase treatment given up to 5 days on top of standard of care (SOC) compared with SOC alone, in patients with acute respiratory distress syndrome (ARDS) triggered by COVID-19.						
27	CAIN457A 2310	A randomized, double-blind, placebo- and active controlled multicenter trial to demonstrate efficacy of subcutaneous secukinumab compared to placebo and etanercept (in a single blinded arm) after twelve weeks of treatment, and to assess the safety, tolerability, and long-term efficacy in subjects from 6 to less than 18 years of age with severe chronic plaque psoriasis	Interventional	III	1-Faculty of Medicine, Clinical Research Center 2-Faculty of Medicine, Dermatology Department, Ain Shams University	Approved 20/94/12 Early terminated 6/2/2023	Treatments of severe chronic plaque psoriasis	**(**Biological) Secukinumab
28	SCTV01E-MRCT-1	A randomized double blind positive controlled phase III clinical trial to evaluate the efficacy and safety of SCTV01E (a covid-19alpha/beta/delta/omicron variants s-trimmer vaccine) in	Interventional	III	1-Katemya Medical Center 2-Egyptian Liver Hospital- Mansoura	Withdrawn 14/1/2023	COVID-19 prophylaxis	(Biological) SCTV01E (a covid-19 alpha/beta/delta/ omicron variants s-trimmer vaccine)

		population previously unvaccinated with COVID-19 vaccine and aged ≥18						(Biological)
29	FUZION CNTO1959CRD	A Phase 3, Randomized, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Efficacy and Safety of Guselkumab in Participants with Fistulizing, Perianal Crohn's Disease ""FUZION CD	Interventional	III	-National Hepatology Tropical Medicine Research Institute 6/9/2023 -CRC, Alexandria university hospital -El Kasr Alinini,Cairo University -MASRI CRC, Ain Shams University Hospital	Approved 13/8/2023	Fistulizing perianal Crohn's disease	Guselkumab (Biological)
30	MP-ADA1-01	A Phase I, randomized, double-blind, 2-arm, parallel group trial to compare pharmacokinetics of Adessia with EU-authorized Humira in healthy male and female "participants	Interventional	I	-CRS clinical research services, Berlin GmbH -CRS clinical research services, Mannheim GmbH	Approved 10/8/2023	Inflammatory disease (Biosimilar to Humira)	Adessia (Biological)
31	MOM-M281-006	Efficacy and Safety of M281 in Adults with Warm Autoimmune Hemolytic Anemia: A Multicenter, Randomized, Double-blind, Placebo-controlled Study with a Long-term Open-label "Extension	Interventional	II\III	-National Cancer Institute -Oncology center, Mansoura University Hospital: -Al Kasr al Eini, Cairo university	Approved 19/7/2023	Warm Autoimmune Hemolytic Anemia	M281 (Biological)

					-Naser institute hospital for research and treatment -CRC, Alexandria university Hospital -CRC, Ain shams university Hospital			
32	CEGA230 B2404	A Phase IV Multicenter Open Label Study to Determine the Safety, Tolerability and Clinical Outcomes Following Oral Administration of Egaten (Triclabandazole) in Patients 6 Years of Age or Older with Fascioliasis (Egaten)	Interventional	IV	1-Cairo University, Al Mounira Children Hospital 2-Alexandria University Clinical Research Center.	Approved 12/4/2021 Ongoing	Fascioliasis	(Pharmaceutical) Triclabandazole (Egaten)
33	CLEE011 A3201C RIGHT Choice	A Phase II Randomized Study of the Combination of Ribociclib Plus Goserelin Acetate with Hormonal Therapy Versus Physician Choice Chemotherapy in Premenopausal or Perimenopausal Patients with Hormone Receptor-Positive/HER2-Negative Inoperable Locally Advanced or Metastatic Breast Cancer - RIGHT Choice Study	Interventional	II	1-Ain Shams University Clinical Research Center, (MASRI – CRC) 2-Baheya Hospital Research Center 3-Cairo University, NEMROCK 4-Nasser Institute Cancer Center	Approved 14/10/2021 Completed 8/1/2023	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy

34	BO40336 ALINA	A Phase III, Open-Label, Randomized Study to Evaluate the Efficacy and Safety of Adjuvant Alectinib Versus Adjuvant Platinum-Based Chemotherapy in Patients with Completely Resected Stage Ib (Tumors ≥ 4 Cm) To Stage IIIa Anaplastic Lymphoma Kinase-Positive Non-Small-Cell Lung Cancer	Interventional	III	1-Cairo University, Kasr Al Eini, Center of Radiation Oncology and Nuclear Medicine	Approved 29/5/2019 Ongoing	Lung Cancer	(Pharmaceutical) Alectinib / Platinum based Chemotherapy
35	Cl_Tr_171 22019 MIRACLE -ALA	A Multicenter, Interventional, Two-Arm, Parallel-Group, Randomized, Double-Blinded, Placebo-Controlled, Phase IV Trial to Evaluate the Efficacy of Alpha-Lipoic Acid in the Treatment of Patients with Symptomatic Diabetic Polyneuropathy in Egypt	Interventional	IV	1-Alexandria University Hospital 2-Ain Shams University Hospital 3-Menoufiya University Hospital 4-Mansoura University Hospital 5-Beni Suif University Hospital	Approved 12/10/2022 Ongoing	Treatment of Symptomatic Diabetic Polyneuropathy	(Pharmaceutical) Alpha-Lipoic Acid (Thiotacid)/ matching placebo
36	M14-430	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Maintenance and Long-Term Extension Study of the Efficacy and Safety of Upadacitinib (ABT-494) in Subjects with Crohn's Disease	Interventional	III	1-Air Force Specialized Hospital 2-National Liver Institute Menoufiya University 3-Alexandria University Clinical Research Center	Approved 2/12/2018 Ongoing	Chron's Disease	(Pharmaceutical) Upadacitinib/ matching placebo

		Who Completed the Studies M14-431 or M14-433			4-Ain Shams University Clinical Research Center (MASRI-CRC)			
37	MK4482-013 MOVe-Ahead	A Phase 3 Multicenter, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Efficacy and Safety of MK-4482 for the Prevention of COVID-19 (Laboratory Confirmed SARS-COV 2 Infection with Symptoms) in Adults.	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC) 2-Air Force Specialized Hospital 3-National Hepatology and Tropical Medicine Research Institute 4-Imbaba Fever Hospital 5-National Center for Allergies and Chest Imbaba	Approved 18/1/2022 Completed 16/11/2022	Prophylaxis of COVID-19	(Pharmaceutical) Molnupiravir/ matching placebo
38	GBT440-032	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Voxelotor (GBT440) in Pediatric Participants with Sickle Cell Disease (HOPE Kids 2)	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC). 2-Alexandria University Clinical Research Center 3-Cairo University Hospital. 4-Zagazig University Hospital.	Approved 31/7/2022 Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo
39	GBT440-034	An Open Label Extension Study of GBT440 Administered Orally to Patients with Sickle Cell Disease who Have	Interventional	III	1-Cairo University, Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 2/8/2022 Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor

		Participated in GBT440 Clinical Trials			3-Alexandria University Clinical Research Center 4-Zagazig University Hospital.			
40	F901318/0032	Open Label Single Arm Phase IIb Study of F901318 as Treatment of Invasive Fungal Infections Due to Lomentospora Prolificans, Seedosporium Spp., Aspengillus Spp., & other Resistant Fungi in Patients Lacking Suitable Alternative	Interventional	IIb	1-Mansoura University Oncology center 2-Alexandria University, Clinical Research Center 3-Nasser Institute 4-Ain Shams University Clinical Research Center, (MASRI – CRC) 5-Air Force specialized Hospital 6-National Cancer Institute 7-Cairo University Kasr Al-Eini, Hospital	Terminated 24/7/2022	Invasive Fungal Infection	(Pharmaceutical) Olorofim
41	CLSYN.1702	A 2x2 factorial randomized controlled trial of CoLchicine and spironolactonE in patients with myocARdial infarction/SYNERGY Stent Registry – Organization to Assess Strategies for Ischemic Syndromes 9	Interventional	III/IV	1-Mansoura University Hospital 2-Suez Canal University Hospital 3-Fayoum General Hospital 4-Tamia Central Hospital 5-El Kharga Specialized Hospital 6-National Heart Institute	Approved 24/7/2022 Ongoing	STEMI/Non-STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/ matching placebo
42	20140106	Phase 1b/2 Study of Carfilzomib in Combination	Interventional	Ib/II	1-Children's Cancer Hospital 57357	Approved	Relapsed or Refractory	(Pharmaceutical)

		with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia				23/8/2022 Withdrawn 19/6/2023	Acute Lymphoplastic Leukemia	Carfilzomib
43	AG348-C-020	A Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of Mitapivat in Subjects with Sickle Cell Disease	Interventional	II/III	1-Alexandria University Clinical Research Center 2-Zagazig University Hospital 3-Cairo University Hospital 4-Mansoura University Hospital 5-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 27/9/2022 Withdrawn 21/8/2023	Sickle Cell Disease	(Pharmaceutical) Mitapivat / matching placebo
44	F901318/0041	A Phase III, adjudicator-blinded, randomised study to evaluate the efficacy and safety of treatment with olorofim versus treatment with AmBisome® followed by standard of care (SOC) in patients with invasive fungal disease (IFD) caused by Aspergillus species	Interventional	III	1-Mansoura University Oncology Center 2-Alexandria University Clinical Research Center 3-Air Force specialized Hospital 4-Ain Shams University, Clinical Research Center (MASRI-CRC) 5-Zagazig University Hospital 6-National Cancer Institute	Approved 11/10/2022	Invasive Fungal Disease caused by Aspergillus species	(Pharmaceutical) Olorofim / Ambisome

					7-Cairo University Kasr Al Eini Hospital 8-Nasser Institute for Research and Treatment			
45	APD334-202	A Multicentre Randomized Double Blinded Parallel Group Study to Assess the Efficacy and Safety of Oral Etrasimod as Induction and Maintenance Therapy for Moderately to Severe Active Crohn's Disease (Etrasimod)	Interventional	III	1-Alexandria University Clinical Research Center 2-Air Force Specialized Hospital 3-National Liver Institute 4-National Hepatology and Tropical Medicine Research Institute (NHTMRI) 4-Cairo University Kasr Al-Eini Hospital 5-Egyptian Liver Research Institute and Hospital 6-Ain Shams University Hospital 7-Theodor Bilharz Research Institute	Approved 23/8/2022 Ongoing	Moderately to Severe Active Crohn's Disease	(Pharmaceutical) Etrasimod / matching placebo
46	EFC17215 LEAP-2-MONO	A Phase 3, Multicenter, Multinational Randomized Double-Blind Double-Dummy, Active Comparator Study to Evaluate the Efficacy and Safety of Venglustat in Adult and Pediatric Patients with Gaucher Disease Type 3	Interventional	III	1-Alexandria University Hospital Clinical Research Center	Approved 24/10/2022	Gaucher Disease Type 3 (GD3)	(Pharmaceutical) Venglustat/ Cerezyme

		(GD3) who Have Reached Therapeutic Goals with Enzyme Replacement Therapy						
47	AG348-C-017	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Non–Transfusion-Dependent Alpha- or Beta-Thalassemia (ENERGIZE)	Interventional	III	1-Cairo University Hospital 2-Ain Shams University Clinical Research Center MASRI-CRC	Approved 2/11/2022 Withdrawn 26/6/2023	Non-Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo
48	AG348-C-018	A Phase 3, Double-blind, Randomized, Placebo-Controlled, Multicenter Study Evaluating the Efficacy and Safety of Mitapivat in Subjects with Transfusion-Dependent Alpha- or Beta-Thalassemia (ENERGIZE-T)	Interventional	III	1-Cairo University Hospital 2-Ain Shams University Clinical Research Center MASRI-CRC	Approved 2/11/2022 Withdrawn 26/6/2023	Transfusion-Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo
49	4202-HEM-301	An Adaptive, Randomized, Placebo-controlled, Double-blind, Multi-center Study of Oral Etavopivat, a Pyruvate Kinase Activator in Patients with Sickle Cell Disease	Interventional	III	1- Alexandria University Clinical Research Center 2-Zagazig University Hospital 3-Cairo University Hospital 4-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved 11/12/2022	Sickle Cell Disease	(Pharmaceutical) Etavopivat / matching placebo

50	GO42784 LIDERA	A Phase III, Randomized, Open-Label, Multicenter Study Evaluating the Efficacy and Safety of Adjuvant Giredestrant Compared with Physician's Choice of Adjuvant Endocrine Monotherapy in Patients with Estrogen Receptor−Positive, Her2-Negative Early Breast Cancer	Interventional	III	1-Alexandria University Hospital 2-Medical Research Institute, Alexandria University 3-Mansoura University Hospital 4-Cairo University Kasr Al- Ainy Hospital 5-Ain Shams University Demerdash Hospital 6- Dar El Salam Cancer Hospital 7- Sohag Oncology Center	Approved 4/12/2022 Ongoing	Estrogen Receptor−Positive, Her2-Negative Early Breast Cancer	(Pharmaceutical) Giredestrant / Physician Choice of Adjuvant Endocrine Monotherapy
51	(ACTIV-2D/A5407)	A Phase 3, Multicenter, Randomized, Double-Blind, 24-Week Study of the Clinical and Antiviral Effect of S-217622 Compared with Placebo in Non-Hospitalized Participants with COVID-19	Interventional	III	1-National Hepatology and Tropical Medicine Research Institute 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center, 4-Air Force Specialized Hospital 5-National Institute for Chest Allergy and Diseases 6-Imbaba Fever Hospital	Approved 31/1/2023 Withdrawn 26/9/2023	Covid-19 treatment	(Pharmaceutical) S-217622 / matching placebo

52	RBSC2161	A Phase 2a Randomized, Double-Blind, Placebo-Controlled Study to Characterize the Pharmacokinetics and Pharmacodynamics of Rifaximin Novel Formulations in Patients with Sickle Cell Disease	Interventional	IIa	1-Cairo University Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Zagazig University Hospital 4-Cairo University Hospital 5-Alexandria University Clinical Research Center	Approved 5/2/2023	Sickle Cell Disease	(Pharmaceutical) Rifaximin / matching placebo
53	ENRICH-AF	Edoxaban for Intracranial Haemorrhage Survivors with Atrial Fibrillation (ENRICH-AF) Edoxaban 60/30mg once daily	Interventional	IV	1-Ain Shams University Clinical Research Center (MASRI-CRC) 2-Zagazig University Hospital 3-Fayoum General Hospital 4-Tanta University Hospital 5-Mansoura University Hospital 6-Ain Shams Specialized Hospital 7-Alexandria University Clinical Research Center 8-Assuit University Hospital	Approved 10/5/2023 Ongoing	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban

54	GN41851 FENHANCE	A phase III multicentre, randomized, double-blind, double-dummy, parallel-group study to evaluate the efficacy and safety of Fenebrutinib compared with Teriflunomide in adult patients with relapsing multiple sclerosis. .	Interventional	III	1-Alexandria University-Clinical Research Center	Approved 26/4/2023	Relapsing multiple sclerosis	(Pharmaceutical) Fenebrutinib/ Teriflunomide/ matching placebo
55	1305-0023 (FIBRONEER –ILD)	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Progressive Fibrosing Interstitial lung diseases (PF-ILDs)	Interventional	III	1-Ain Shams University Clinical Research Center (MASRI-CRC) 2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Aini Hospital	Approved 1/6/2023	Progressive Fibrosing Interstitial lung diseases (PF- ILDs)	(Pharmaceutical) BI 1015550 / matching placebo
56	1305-0014 (FIBRONEER – IPF)	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Idiopathic Pulmonary Fibrosis (IPF)	Interventional	III	1- Ain Shams University Clinical Research Center (MASRI-CRC) 2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Ainy Hospital	Approved 1/6/2023	Idiopathic Pulmonary Fibrosis (IPF)	(Pharmaceutical) BI 1015550 / matching placebo

57	GBT440-038	An Open-Label Extension Study of Voxelotor Administered Orally to Paediatric Participants with Sickle Cell Disease Who Have Participated in Voxelotor Clinical Trials	Interventional	III	1-Alexandria University Clinical Research Center 2- Zagazig University Hospital 3-Cairo University, Abu El Rich Hospital.	Approved 30/3/2023	Sickle Cell Disease	(Pharmaceutical) Voxelotor
58	4202-HEM-201	A Phase 2 Open-Label Study to Evaluate Safety and Clinical Activity of FT-4202 in Patients with Thalassemia or Sickle Cell Disease	Interventional	II	1- Cairo University, Abu El-Rich Children Hospital. 2-Cairo University, Kasr Al Eini Hospital.	Approved 1/6/2023	Thalassemia or Sickle Cell Disease	(Pharmaceutical) Etavopivat
59	EFC16035 (PERSEUS)	A Phase 3, Randomized, Double-Blind, Efficacy and Safety Study Comparing SAR442168 to Placebo in Participants with Primary Progressive Multiple Sclerosis	Interventional	III	1-Alexandria University Clinical Research Center	Approved 10/8/2023	Primary Progressive Multiple Sclerosis	(Pharmaceutical) Tolebrutinib/Matching Placebo
60	MD-004	Open labelled non randomized self-controlled study to evaluate the safety and performance of Ezvent in hospitalized mechanically ventilated patients	Interventional	III	1-Kasr Al-Aini university Hospital	Approved 28/8/2022 Ongoing	Hospitalized mechanically ventilated patients	Medical device (Ezvent)
61	COAV101 B12301	A randomized sham controlled double –blind study to evaluate the efficacy and safety of intrathecal (IT)	Interventional	III	-Ain Shams University Specialized Hospital	Approved 2-8-2022 Ongoing	type 2 spinal muscular atrophy (SMA)	Innovative QAV101 (Zolgensma)

		QAV101 in patients with later onset type 2 spinal muscular atrophy (SMA) who are ≥2 to <18 years of age, treatment naïve sitting and never ambulatory						(Onasemnogene abeparvovec)
62	Urso-003	Multi-Center, randomized, control, phase IV trial to compare the efficacy & safety of Ursoplus® capsules (UDCA 250mg & Silymarin 140mg) versus UDCA alone versus Placebo among Compensated Chronic Liver Disease Patients	Interventional	IV	- AFSH - Faculty of Medicine, Helwan University	Approved 18-9-2023 Ongoing	Compensated Chronic Liver Disease Patients	Innovative Ursoplus® capsules/ Ursofalk® capsules
63	Cipro-001	Single center, Open Label, controlled Study to assess the safety & efficacy of Oral Ciprodiazole ® Tablets (Ciprofolxacin/ Metronidazole) versus currently used Ciprofloxacin Tablets & Metronidazole tablets in pelvi-abdominal infections and following IV antibiotics in post-operative period, for pelvi-abdominal surgeries or acute conditions	Interventional	IV	- Menoufia University/ General Syrgery	Suspended 12-9-2023	Pelvi-abdominal infections and following IV antibiotics in post-operative period, for pelvi-abdominal surgeries or acute conditions	Innovative Ciprodiazole ® Tablets (Ciprofolxacin/ Metronidazole)

64	Thrombex	A Prospective, Single- Center, Phase IV Interventional, Single Arm Trial for the Evaluation of subcutaneous recombinant Hirudin 15 mg (RB variant) in prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations	Interventional	IV	-Alexandria university (El-Hadra Hospital)	Withdrawal 28-8-2023	prophylaxis of Deep Vein Thrombosis (DVT) post major orthopedic operations	Innovative Thrombex