GA of Clinical Trials

Protocols & Studies Follow up Administration





جمهورية مصر العربية هيئة الدواء المصرية الادارة المركزية للمستحضرات الحيوية المبتكرة والدراسات الاكلينيكية الإدارة العامة للدراسات الإكلينيكية إدارة البروتوكولات و متابعة إجراء الدراسات

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	Completed	moderately to severely active Crohn's disease who failed prior biologic treatment	(Biological) Risankizumab

Bio-Inn



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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 M15- 991; or completed M15-989	Interventional	III	Two sites at Faculty of Medicine, CRC, Alexandria University	Ongoing	Crohn's disease	(Biological) Risankizumab
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	Ongoing	Ulcerative Colitis	(Biological) Risankizumab





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4	M16-067	Multicenter	Interventional	III	1- CRC, Alexandria	Ongoing	Active	(Biological)
_	1,110 00,	randomized double-	222021 / 0220202020		University	011901119	ulcerative	(2101081041)
		blind placebo			2-National Liver		colitis.	Risankizumab
		controlled induction			Institute, Menoufia			
		study to evaluate the			University			
		efficacy and safety of			3-Air Force Specialized			
		Risankizumab in			Hospital			
		subjects with			4-Faculty of Medicine,			
		moderately to severely			Alexandria University			
		active ulcerative			·			
		colitis.						
5	QGE031	A Multicenter,	Interventional	III	1-Faculty of medicine,	Withdrawn	Chronic	(Biological)
		Randomized, double-			Alexandria university		spontaneous	
		blind active and			2-Faculty of medicine,		Urticaria	Ligelizumab
		placebo-controlled			Ain Shams University			
		study to investigate						
		the efficacy and safety						
		of Ligelizumab in the						
		treatment of chronic						
		spontaneous urticaria						
		in adolescents and						
		adults in adequately						
		controlled with H1						
		antihistamines						

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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 university	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	Interventional	Π	Abu El Resh Children Hospital	Withdrawn	Sickle cell anaemia	(Biological) Crizanlizumab

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		sickle cell nephropathy						
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 cell disease patients with vaso occlusive crisis	Interventional	III	1-Faculty of medicine, Alexandria university 2-Faculty of medicine, Ain Shams university	Withdrawn	Sickle cell anaemia	(Biological) Crizanlizumab
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	IIIIb	1-Sayed Galal Hospital 2-Faculty of medicine, Alexandria university 3-CRC, MASRI, Ain Shams University	Withdrawn	Primary progressive multiple sclerosis	(Biological) Ocrelizumab

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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	Withdrawn	Generalized pustular psoriasis	(Biological) Spesolimab
11	05-Gam-COVID- Vac-2020	A Phase III, randomized, double blind, placebocontrolled 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	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	Interventional	III	1-Vacsera Health care facility 2-Ktameya medical center	Completed	COVID-19 Prophylaxis	(Biological) Inactivated SARS- COV-1 Vaccine

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13	D910DC00001 (Emerald-2)	efficacy, safety and immunogenicity of Inactivated SARS-COV-2 Vaccines in healthy population aged 18 years old and above 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	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	Ongoing	Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation	(Biological) Durvalumab\ Bevacizumab
14	01-Sputnik-Light-	resection or ablation A phase III,	Interventional	III	1- National hepatology	Completed	COVID-19	(Biological)
14	2021	randomized, double-	interventional	111	and tropical medicine	Completed	Prophylaxis	(Diological)
		blind, placebo- controlled international multi-site			center 2-Katemeya medical center			Sputnik Light vector vaccine

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		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						
15	KATE-3	A randomized, multicenter, double blind, placebo-controlled phase III study of 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	Interventional	III	1-Kasr Al Ainy hospital 2-Shefaa Al orman hospital 3-Baheya hopsital	Withdrawn	HER2-positive and PD-L1- positive locally advanced or metastatic breast cancer	(Biological) Trastuzumab Emtansine/ Atezolizumab

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		Trastuzumab + Atezolizumab and Taxane- based therapy						
16	CAIN457P12301	A randomized, double blind, placebo-controlled, parallel group, phase III multicenter 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	Active ankylosis spondylitis	(Biological) Secukinumab
17	TG2101V01	A Global, Multi- Center, Randomized, Double-Blind, Placebo-Controlled, Phase III Clinical Study to Evaluate the	Interventional	III	National Hepatology and Tropical Medicine Research institute	Withdrawn	COVID-19 Prophylaxis	(Biological) Recombinant SARS-CoV-2 Fusion Protein Vaccine (V-01)





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		Efficacy, Safety and Immunogenicity of Recombinant SARS-CoV-2 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	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	Interventional	I	National research center	Suspended	Covid-19 Prophylaxis	(Biological) Inactivated SARS-CoV-2 Vaccine





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20	SPHINX-EGYPT SPHINX22122020	Against COVID-19 in Healthy Adults Safety and Immunogenicity Study of EgyVax Vaccine Candidate for Prophylaxis of SARS- CoV-2 Infection (COVID-19)	Interventional	I	Al-Manial specialized university Hospital	Completed	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 disease experiencing Vaso-occlusive crisis	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.	Ongoing	sickle cell disease patients with Vaso-occlusive crisis	(Biological) Inclacumab
22	GBT2104-132	A Randomized, Double-blind,	Interventional	III	1. Faculty of medicine, Mansoura University	Withdrawn	Sickle cell disease	(Biological)

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

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					8- Cairo University, Hematology department.			
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	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	Withdrawal	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,	Interventional	IIb/III	1.National Hepatology and Tropical Medicine Research Institute 2.Abbasia Fever Hospital 3.Imbaba Fever Hospital	Withdrawal	Respiratory distress syndrome (ARDS) triggered by COVID-19	(Biological) Alteplase





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		sequential, parallel- group adaptive study to evaluate the efficacy 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	CAIN457A2310	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	Interventional	III	1-Faculty of Medicine, Clinical Research Center 2-Faculty of Medicine, Dermatology Department, Ain Shams University	Terminated	Treatments of severe chronic plaque psoriasis	(Biological) Secukinumab





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		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						
2	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/omi cron variants s-trimmer vaccine) in population previously unvaccinated with COVID-19 vaccine and aged ≥18	Interventional	III	1-Katemya Medical Center 2-Egyptian Liver Hospital- Mansoura	withdrawal	COVID-19 prophylaxis	(Biological) SCTV01E (a covid-19 alpha/beta/delta/ omicron variants s- trimmer vaccine) (Biological)

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1	CEGA230B2404	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.	Ongoing	Fascioliasis	(Pharmaceutical) Triclabandazole (Egaten)
2	CLEE011A3201C 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	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	Completed	HER-2 Negative Breast Cancer	(Pharmaceutical) Ribociclib Plus Goserelin / Physician Choice Chemotherapy





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		Hormone Receptor- Positive/HER2- Negative Inoperable Locally Advanced or Metastatic Breast Cancer - RIGHT Choice Study						
3	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	Ongoing	Lung Cancer	(Pharmaceutical) Alectinib / Platinum based Chemotherapy

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4	Cl_Tr_17122019 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	Interventional	IV	1-Alexandria University Hospital 2-Ain Shams University Hospital 3-Menoufiya University Hospital 4-Mansoura University Hospital 5-Beni Suif University Hospital	Ongoing	Treatment of Symptomatic Diabetic Polyneuropath y	(Pharmaceutical) Alpha-Lipoic Acid (Thiotacid)/ matching placebo
5	M14-430	Egypt 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 Who	Interventional	III	1-Air Force Specialized Hospital 2-National Liver Institute Menoufiya University 3-Alexandria University Clinical Research Center 4-Ain Shams University Clinical Research Center (MASRI-CRC)	Ongoing	Chron's Disease	(Pharmaceutical) Upadacitinib/ matching placebo

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6	MK4482-013 MOVe-Ahead	Completed the Studies M14-431 or M14-433 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	Completed	Prophylaxis of COVID-19	(Pharmaceutical) Molnupiravir/ matching placebo
7	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.	Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor/ matching placebo





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8	GBT440-034	An Open Label Extension Study of GBT440 Administered Orally to Patients with Sickle Cell Disease who Have Participated in GBT440 Clinical Trials	Interventional	III	1-Cairo University, Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC) 3-Alexandria University Clinical Research Center 4-Zagazig University Hospital.	Ongoing	Sickle Cell Disease	(Pharmaceutical) Voxelotor
9	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	Invasive Fungal Infection	(Pharmaceutical) Olorofim

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10	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	Ongoing	STEMI/Non- STEMI Myocardial Infarction	(Pharmaceutical) Colchicine, Spironolactone/ matching placebo
11	20140106	Phase 1b/2 Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia	Interventional	Ib/II	1-Children's Cancer Hospital 57357	Withdrawn	Relapsed or Refractory Acute Lymphoplastic Leukemia	(Pharmaceutical) Carfilzomib
12	AG348-C-020	A Phase 2/3, Double- Blind, Randomized, Placebo-Controlled,	Interventional	II/III	1-Alexandria University Clinical Research Center	Approved	Sickle Cell Disease	(Pharmaceutical) Mitapivat /

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		Multicentre Study to Evaluate the Efficacy and Safety of Mitapivat in Subjects with Sickle Cell Disease			2-Zagazig University Hospital 3-Cairo University Hospital 4-Mansoura University Hospital 5-Ain Shams University Clinical Research Center (MASRI-CRC)			matching placebo
13	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 7-Cairo University Kasr Al Eini Hospital 8-Nasser Institute for Research and Treatment	Approved	Invasive Fungal Disease caused by Aspergillus species	(Pharmaceutical) Olorofim / Ambisome

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14	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	Ongoing	Moderately to Severe Active Crohn's Disease	(Pharmaceutical) Etrasimod / matching placebo
15	EFC17215 LEAP-2-MONO	A Phase 3, Multicentre, Multinational Randomized Double- Blind Double- Dummy, Active Comparator Study to	Interventional	III	1-Alexandria University Hospital Clinical Research Center	Approved	Gaucher Disease Type 3 (GD3)	(Pharmaceutical) Venglustat/ Cerezyme

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16	AG348-C-017	Evaluate the Efficacy and Safety of Venglustat in Adult and Pediatric Patients with Gaucher Disease Type 3 (GD3) who Have Reached Therapeutic Goals with Enzyme Replacement Therapy A Phase 3, Doubleblind, 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	Withdrawn	Non- Transfusion- Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo
17	AG348-C-018	A Phase 3, Double- blind, Randomized, Placebo-Controlled, Multicenter Study	Interventional	III	1-Cairo University Hospital	Withdrawn	Transfusion- Dependent Alpha or Beta Thalassemia	(Pharmaceutical) Mitapivat / matching placebo

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		Evaluating the Efficacy and Safety of Mitapivat in Subjects with Transfusion- Dependent Alpha- or Beta-Thalassemia (ENERGIZE-T)			2-Ain Shams University Clinical Research Center MASRI-CRC			
18	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	Sickle Cell Disease	(Pharmaceutical) Etavopivat / matching placebo
19	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	Interventional	III	1-Alexandria University Hospital 2-Medical Research Institute, Alexandria University 3-Mansoura University Hospital 4-Cairo University Kasr Al- Ainy Hospital	Ongoing	Estrogen Receptor—Posi tive, Her2- Negative Early Breast Cancer	(Pharmaceutical) Giredestrant / Physician Choice of Adjuvant Endocrine Monotherapy

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		Patients with Estrogen Receptor—Positive, Her2-Negative Early Breast Cancer			5-Ain Shams University Demerdash Hospital			
20	(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	Covid-19 treatment	(Pharmaceutical) S-217622 / matching placebo
21	RBSC2161	A Phase 2a Randomized, Double- Blind, Placebo- Controlled Study to Characterize the	Interventional	IIa	1-Cairo University Abu El Rich Hospital. 2-Ain Shams University Clinical Research Center (MASRI-CRC)	Approved	Sickle Cell Disease	(Pharmaceutical) Rifaximin / matching placebo

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		Pharmacokinetics and Pharmacodynamics of Rifaximin Novel Formulations in Patients with Sickle Cell Disease			3-Zagazig University Hospital 4-Cairo University Hospital 5-Alexandria University Clinical Research Center			
22	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	Ongoing	Atrial Fibrillation in patients with previous Intracranial Haemorrhage	(Pharmaceutical) Edoxaban

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23	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	Relapsing multiple sclerosis	(Pharmaceutical) Fenebrutinib/ Teriflunomide/ matching placebo
24	1305-0023 (FIBRONEER – ILD)	A double blind, randomized, placebocontrolled 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	Progressive Fibrosing Interstitial lung diseases (PF- ILDs)	(Pharmaceutical) BI 1015550 / matching placebo
25	1305-0014	A double blind, randomized, placebo- controlled trial	Interventional	III	1- Ain Shams University Clinical Research Center (MASRI-CRC)	Approved	Idiopathic Pulmonary Fibrosis (IPF)	(Pharmaceutical)

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	(FIBRONEER – IPF)	evaluating the efficacy and safety of BI 1015550 over at least 52 weeks in patients with Idiopathic Pulmonary Fibrosis (IPF)			2- Alexandria University Clinical Research Center 3- Air Force Specialized Hospital 4- Cairo University, Kasr Al Ainy Hospital			BI 1015550 / matching placebo
26	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	Sickle Cell Disease	(Pharmaceutical) Voxelotor
27	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	Thalassemia or Sickle Cell Disease	(Pharmaceutical) Etavopivat

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1	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	Hospitalized mechanically ventilated patients	Medical device (Ezvent)
1	COAV101B12301	A randomized sham controlled double – blind study to evaluate the efficacy and safety of intrathecal (IT) 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	Interventional	III	-Ain Shams University Specialized Hospital	Ongoing	type 2 spinal muscular atrophy (SMA)	Innovative QAV101 (Zolgensma) (Onasemnogene abeparvovec)
2	Urso-003	Multi-Center, randomized, control, phase IV trial to compare the efficacy & safety of Ursoplus®	Interventional	IV	- AFSH - Faculty of Medicine, Helwan University	Ongoing	Compensated Chronic Liver Diseased Patients	Innovative Ursoplus





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		capsules (UDCA 250mg & Silymarin 140mg) versus UDCA alone versus Placebo among Compensated Chronic Liver Diseased Patients						
3	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 pelviabdominal infections and following IV antibiotics in post- operative period, for pelvi-abdominal surgeries or acute conditions	Interventional	IV	- Menoufia University/ General Syrgery	Ongoing	Pelviabdominal infections and following IV antibiotics in post-operative period, for pelviabdominal surgeries or acute conditions	Innovative Ciprodiazole

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هيئة الدواء المصرية الادارة المركزية للمستحضرات الحيوية المبتكرة والدراسات الاكلينيكية الإدارة العامة للدراسات الإكلينيكية إدارة البروتوكولات و متابعة إجراء الدراسات

جمهورية مصر العربية

GA of Clinical Trials
Protocols & Studies Follow up
Administration

4	Thrombex	A Prospective, Single- Center, Phase IV	Interventional	IV	-Alexandria university (El-Hadra Hospital)	Ongoing	prophylaxis of Deep Vein	Innovative
		Interventional, Single Arm Trial for the			(21 11uu u 110sp1uu)		Thrombosis	Thrombex
		Evaluation of					(DVT) post major	
		subcutaneous recombinant Hirudin					orthopedic operations	
		15 mg (RB variant) in					Ι	
		prophylaxis of Deep Vein Thrombosis						
		(DVT) post major orthopedic operations						
		orthopedic operations						