Bio-Inn



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

GA of Clinical Trials Protocols & Studies Follow up Administration

Clinical Trials Registry at EDA

SN	Submission date	Study code (specified as per the submitted protocol)	Sponsor/ Cro	Study title	Study type: -interventional	Study phase (I, II, III, OR IV)	Sites/activation date "at which the clinical trials will be conducted in Egypt"	Status/date: -approved - recruiting -recruitment completion -completed -withdrawn -suspended -terminated	Conditions / therapeutic area	Interventions "used imps & its type (biological, pharmaceutical, innovative, herbal, or medical device)
1	27\12\2018	M15-991	Sponsor Abbvie	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, faculty of medicine, alexandria university 2-crc, faculty of medicine, alexandria university 3-faculty of medicine, cairo university 4- masri-crc, ain shams university 5-national hepatology and tropical medicine institute 6-faculty of medicine, zagazig university	Completed	Moderately to severely active crohn's disease who failed prior biologic treatment	(biological) Risankizumab
2	27\12\2018	M16-000	Sponsor Abbvie	A multicenter, randomized, double- blind, placebo-	Interventional	III	Two sites at faculty of medicine, crc,	Approved 26/3/2019 Recruiting	Crohn's disease	(biological) Risankizumab

Color Indicator

Green Biological
Blue Pharmaceutical
Orange Medical Device
Gray Innovative
Red Herbal

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				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			alexandria university			
3	28\2\2019	M16-066	Sponsor Abbvie	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, crc, alexandria university 2-crc, alexandria university 3-air force specialized hospital research 4- national liver institute, menoufia university	Approved 10/6/2019 Recruiting	Ulcerative colitis	(biological) Risankizumab
4	28\2\2019	M16-067	Sponsor Abbvie	Multicenter randomized double- blind placebo- controlled induction study to evaluate the efficacy and safety of risankizumab in subjects with	Interventional	III	1- crc, faculty of medicine, alexandria university 2-national liver institute, menoufia university 3-air force specialized hospital	Approved 10/6/2019 Completed: 30/11/2023	Active ulcerative colitis.	(biological) Risankizumab

Color Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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				moderately to severely active ulcerative colitis.			4-faculty of medicine, crc, alexandria university			
5	7/5/2019	Qge031	Sponsor: novartis	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 adequately controlled with h1 antihistamines	Interventional	III	1-faculty of medicine, alexandria university 2-faculty of medicine, ain shams university	Withdrawal 31/8/2020	Chronic spontaneous urticaria	(biological) Ligelizumab
6	18/9/2019	Artemisdm "lps15396"	Sanovi	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	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	Approved 9/2/2020 Withdrawal	Type 2 diabetes mellitus	(biological) Insulin glargine "toujeo"

Color Indicator

Green	Biological
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Red	Herbal

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				uncontrolled on						
				basal insulin						
7	18/11/2019	Stand	Novartis	A phase ii,	Interventional	II	1-abu el resh	Approved	Sickle cell	(biological)
				multicenter,			children hospital	5/5/2020	anemia	
				randomized, open						Crizanlizumab
				label, two arm study						
				comparing the effect				Withdrawal		
				of crizanlizumab+				3/8/2021		
				soc alone on renal						
				function in sickle						
				cell disease patients						
				≥16 years with						
				chronic kidney						
				disease due to sickle						
				cell nephropathy						
8	24/3/2020	Stead fast	Sponsor:	A phase iii,	Interventional	III	1-faculty of	Approved	Sickle cell	(biological)
			Novartis	multicenter, double-			medicine, alexandria	20/2/2020	anemia	(* * * * * * * * * * * * * * * * * * *
				blind study to assess			university			Crizanlizumab
				efficacy and safety			2-faculty of			CIIEMIIIE
				of two doses of			medicine, ain shams	Withdrawal		
				crizanlizumab vs			university	3/8/2021		
				placebo with or			difficulty	3/0/2021		
				without hydroxyurea						
				/ hydroxycarbamide						
				therapy, in						
				adolescent and adult						
				sickle cell disease						
				patients with vaso-						
0	20/2/2020	Wa40404	Roche	occlusive crisis	Intomiontional	IIIB	1 saved as lal	Ammorrad	Derivation	(higheries1)
9	30/3/2020	w a40404	Roche	A phase iii b	Interventional	ШВ	1-sayed galal	Approved	Primary	(biological)
				multicenter,			hospital	23/8/2020	progressive	O a ma 1 i m m 1
				randomized, double-			2-faculty of		multiple	Ocrelizumab

Color Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
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					blind, placebo- controlled study to evaluate the efficacy and safety of ocrelizumab in adults with primary progressive multiple sclerosis			medicine, alexandria university 3-crc, masri, ain shams university	Withdrawal 25/8/2021	sclerosis	
1	0	14\9\2020	1368-0025	Boehringer ingelheim	Open label long term extension study to assess the safety and efficacy of bi655130 treatment in patients with generalized pustular psoriasis	Interventional	IIB	1-dermatology department, faculty of medicine, alexandria university hospital	Approved 18/5/2021 Withdrawal 31/10/2021	Generalized pustular psoriasis	(biological) Spesolimab
1	1	21/9/2020	05-gam- covid-vac- 2020	Sponsor: russian direct investment fund (rdif)	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	Ш	1-national liver institute, menoufia university 2-crc, faculty of medicine, alexandria university 3- crc, masri, ain shams university	Withdrawn 12/6/2022	Covid-19 prophylaxis	(biological) Russian gam- covid-vac combine vector vaccine
1	2	22/9/2020	Cnbg2020 003sq	China national biotec	Multicenter, randomized, double blind, parallel	Interventional	III	1-vacsera health care facility 2-ktameya medical	Approved 28/3/2022	Covid-19 prophylaxis	(biological)

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			group company limited Wuhan institute of biological products co. Ltd beijin Institute of biological products Co.ltd	placebo controlled, phase iii clinical trial to evaluate the protective efficacy, safety and immunogenicity of inactivated sars-cov- 2 vaccines in healthy population aged 18 years old and above			center	Completed 31/7/2022		Inactivated sars-cov-1 vaccine
13	13/4/2021	D910dc00 001 (emerald- 2)	Sponsor: Astrazenec a Cro: iqvia	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	Interventional	III	1-crc, faculty of medicine, alexandria university hospital 2-national liver institute-menoufia university 3-national hepatology & tropical medicine research institute 4-air force specialized hospital 5-faculty of medicine, assuit	Approved 12/12/2021 Recruiting	Hepatocellular carcinoma patients at high risk of recurrence after curative hepatic resection or ablation	(biological) Durvalumab\ bevacizumab
Color	Green	Biologi	cal	QF: Bio Inn.231.0	1 Issue/	Rev No.: 2		28/03/2024	Rev Date://	Page 6 of 34

Indicator Blue

Pharmaceutical Orange **Medical Device** Gray Innovative Red Herbal





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				curative hepatic			university			
				resection or ablation			university			
- 4	10/7/2001	0.4	~		·				G 1110	4.1.1.
14	19/5/2021	01-sputnik-light-2021	Sponsor: Human vaccine llc (global), russian ministry of healthcare – gamalya (local) Cro: pdc	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	25/5/2021	Kate-3	Sponsor: Roche	A randomized, multi-center, 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-11- positive locally advanced or	Interventional	III	1-faculty of medicine, kasr alainy hospital 2-shefaa al-orman hospital 3-baheya hospital	Approved 5/12/2021 Withdrawal 19/12/2022	Her2-positive and pd-11- positive locally advanced or metastatic breast cancer	(biological) Trastuzumab emtansine/ Atezolizumab

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_											
	16				metastatic breast cancer who have received prior trastuzumab + atezolizumab and taxane- based therapy		W				
	16	27/5/2021	Cain457p1 2301	Sponsor: novartis	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 nonradiographic axial spondylo arthritis	Interventional	III	1-crc, faculty of medicine, alexandrian university	Withdrawal 3/11/2021	Active ankylosis spondylitis	(biological) Secukinumab
	17	5/8/2021	Tg2101v01	Sponsor: Livzon mabpharm inc.	A global, multi- center, randomized, double-blind, placebo-controlled, phase iii clinical study to evaluate the efficacy, safety and	Interventional	III	1-national hepatology And tropical Medicine research Institute (nhtmri)	Withdrawal 16/1/2022	Covid-19 prophylaxis	(biological) Recombinant sars- cov-2 fusion protein vaccine (v-01)

Color **Indicator**

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				immunogenicity of recombinant sars-cov-2 fusion protein vaccine (v-01) in adults aged 18 years and older",						
18	18/8/2021	Covid_vac c_1	Sponsor: Roche	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	2/9/2021	Covid_vac c_1	Sponsor: national research center Cro: clinmax	A phase 1 clinical trial to evaluate the safety, tolerability, and immunogenicity of inactivated sarscov-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	17/1/2022	Sphinx- egypt sphinx221 22020	Sponsor: - eva pharma - vsvri - supreme	Safety and immunogenicity study of egyvax vaccine candidate for prophylaxis of	Interventional	I	Al-manial specialized university hospital, cairo university hospitals	Approved 3/2/2022 Database lock	Covid-19 prophylaxis	(biological) Egyvax

Color Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
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21 Color	4/11/2021 Green	Gbt2104- 131	university hospitals - ministry of higher education and scientific research Cro: dataclin Sponsor: Global blood therapeutic s inc. \ pfizer Cro: mct	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 Rev No.: 2	1-faculty of medicine, mansoura university 2-faculty of medicine, zagazig university 3-masri-crc, faculty of medicine, ain shams university hospital 4-crc, alexandria university 5- pediatric hematology department, alexandria university 6. Crc, faculty of medicine, cairo university, abo elresh hospital 7- crc, cairo 10 Issue Date: 2	Approved 14/6/2022 Recruitment Completion	Sickle cell disease patients with vaso-occlusive crisis	(biological) Inclacumab
			hospitals	sars-cov-2 infection (covid-19)				26/9/2023		
			of higher education							
			scientific							
21	4/11/2021	Ch+2104	dataclin	A wondomized	Intomontional	ш	1 faculty of	Ammoved	Sightle coll	(high gigs)
21	4/11/2U21		Global blood	double blinded placebo controlled	mici ventional	111	medicine, mansoura university		disease patients with	_
			s inc. \	access the safety and efficacy of			medicine, zagazig university		occlusive	
			Cro: mct	participants with			of medicine, ain	Completion		
				experiencing vaso-			hospital 4-crc, alexandria			
							5- pediatric			
							department, alexandria			
							6. Crc, faculty of			
							university, abo el-			
Color	Green	Biologi	cal	OF: Bio Inn 231 01	Icene/ E	Rev No · 2	7- crc, cairo	8/03/2024 R	ev Date://	Page 10 of 34

Color Indicator

Green Biological
Blue Pharmaceutical
Orange Medical Device
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							university			
							8- hematology			
							department, cairo			
							university hospital			
22		Gbt2104-		A randomized,	Interventional	III	1. Faculty of	Approved	Sickle cell	(biological)
	4/1/2022	132	Global	double-blind,			medicine, mansoura	14/6/2022	disease	
			blood	placebo-controlled,			university		patients with	Inclacumab
			therapeutic	multicenter study of			2. Faculty of		vaso-	
			s inc.\	a single dose of			medicine, zagazig		occlusive	
			pfizer	inclacumab to			university	Withdrawal	crisis	
			•	reduce re-admission			3. Masri, crc, ain	29/6/2023		
				in participants with			shams university			
			Cro: mct	sickle cell disease			4.hematology unit,			
				and recurrent vaso-			internal medical			
				occlusive crises			department, crc,			
				(gbt-132)			faculty of medicine			
				(800 102)			alexandria			
							university hospital			
							5- hematology			
							department,			
							alexandria			
							university hospital			
							6. Cairo university,			
							abo el-resh hospital			
							7- crc, cairo			
							university			
							8- cairo university,			
							hematology			
							department.		~	
23		Gbt2104-	Global	An open-label	Interventional	III	1. Faculty of	Approved	Sickle cell	
	28/11/2021	133	blood	extension study to			medicine, mansoura	14/6/2022	disease	(biological)
			therapeutic	evaluate the long-			university			

Color Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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			s inc.\	term safety of			2. Faculty of	Withdrawal		Inclacumab/
			pfizer	inclacumab			medicine, zagazig	17/12/2023		Placebo
				administered to			university			
				participants with			3. Masri, crc, ain			
			Cro: mct	sickle cell disease			shams university			
				who have			4.hematology unit,			
				participated in an			internal medical			
				inclacumab clinical			department, crc,			
				trial			faculty of medicine			
							alexandria			
							university hospital			
							5- hematology			
							department,			
							alexandria			
							university hospital			
							6. Cairo university,			
							abo el-resh hospital			
							7- crc, cairo			
							university			
							8- cairo university,			
							hematology			
							department.			
24		Consonanc	Sponsor:	An open-label,	Interventional	III	1-crc, faculty of	Approved	Progressive	(biological)
	8\6\2022	e-mn39159	F.hoffman	single-arm 4-year			medicine,	20/9/2022	multiple	
			n-la roche	study to evaluate			alexandria		sclerosis	Ocrelizumab
			ltd	effectiveness and			university, crc			
				safety of			2-masri-crc,faculty	Recruiting		
			Cro:	Ocrelizumab			of medicine, ain			
			Roche	treatment in patients			shams university			
			egypt llc &	with progressive			hospital			
			iqvia (for	multiple sclerosis						
			monitoring							
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COIOL	Green	Biologi	cai	QF: Bio Inn.231.01	Issue/ R	ev No.: 2	0 Issue Date: 2	8/U3/2U24 R	lev Date:/	Page 12 of 34

Indicator Blue

Pharmaceutical Orange **Medical Device** Gray Innovative Herbal Red





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			only)							
25	9\2\2022	20200404 (imbcam	Sponsor: institute of medical biology chinese academy of medical sciences Cro: pdc	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- national hepatology and tropical medicine institute	Withdrawal 24/2/2022	Covid-19 prophylaxis	(biological) Inactivated sars- cov-2 vaccine
26	10/5/2022	Tristards- 0135-0347	Sponsor: boehringer ingelheim Cro: mct	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 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)	Interventional	IIB/III	1.national hepatology and tropical medicine research institute 2.abbasia fever hospital 3.imbaba fever hospital	Withdrawal 20/7/2022	Respiratory distress syndrome (ards) triggered by covid-19	(biological) Alteplase

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		_								
				triggered by covid- 19.						
27	14/8/2022	Cain457a2 310	Sponsor: novartis Cro: mct	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	Ш	1-crc, faculty of medicine, alexandria university hospital 2-dermatology department, faculty of medicine, ain shams university hospital	Approved 4/12/2022 Early terminated by sponsor 31/3/2023	Treatments of severe chronic plaque psoriasis	(biological) Secukinumab
28	8/11/2022	Sctv01e- mrct-1	Sponsor: sinocelltec h Cro: pdc	A randomized double blind positive controlled phase iii clinical trial to evaluate the efficacy and safety of sctv01e (a covid-19alpha/beta/delta/o micron variants s-	Interventional	III	1-katemya medical center 2-egyptian liver research institute and hospital	Withdrawal 14/1/2023	Covid-19 Prophylaxis	(biological) Sctv01e (a covid-19 alpha/beta/delta/ Omicron variants s-trimmer vaccine) (biological)

Color Indicator

Green	Biological
Blue	Pharmaceutical
Orange	Medical Device
Gray	Innovative
Red	Herbal

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				trimmer vaccine) in population previously unvaccinated with covid-19 vaccine and aged ≥18						
29	6/6/2023	Fuzion Cnto1959c rd	Sponsor: Janssen Cro: Mct	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	1.national hepatology tropical medicine research institute 2.crc, faculty of medicine alexandria university hospital, (two sites) 3. Department of internal medicine, el kasr al aini, cairo university 4. Masri crc, faculty of medicine, ain shams university hospital	Approved 13/8/2023	Fistulizing perianal crohn's disease	Guselkumab (biological)
30	Mp-ada1- 01	14/5/2023	Sponsor: Minapharm Cro: Crs clinical research services berlin gmbh	A phase i, randomized, double-blind, 2-arm, parallel group trial to compare pharmacokinetics of adessia with euauthorized 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)

Color Indicator

Green	Biological
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Gray	Innovative
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31		Mom-	Sponsor:	Efficacy and safety	Interventional	II/III	-national cancer	Approved	Warm	M281
	4/5/2023	m281-006	Janssen	of m281 in adults			institute, cairo	19/7/2023	autoimmune	
				with warm			university		hemolytic	(biological)
			Cro:	autoimmune			-oncology center,		anemia	
			Mct	hemolytic anemia: a			mansoura university			
				multicenter,			hospital			
				randomized, double-			-department of			
				blind, placebo-			internal medicine, al			
				controlled study			kasr al eini, cairo			
				with a long-term			university			
				open-label			-naser institute			
				extension"			hospital for research			
							and treatment			
							-crc, faculty of			
							medicine,			
							alexandria			
							university hospital			
							-crc, faculty of			
							medicine, ain shams			
							university hospital			
32	9\10/2023	Emerald-3)	Sponsor:	A phase III, randomiz	Interventional	III	- air force	Approved	Locoregional	
		D910vc00	astrazeneca	open-label, sponsor-			specialized hospital	8/2/2024	hepatocellular	(biological)
	Shift to	001	Cro: iqivia	blinded, multicenter			- oncology		carcinoma	
	amendment			study of durvalumab			department, faculty			valumab /
	submission			in combination			of medicine, alex			melimumab/
	26\12\2023			With tremelimumab			university			vatinib /tace
							- egyptian liver			
				± lenvatinib given			hospital			
				Concurrently with			- national			
				transarterial			hepatology and			
				chemoembolization			tropical medicine			
				(tace) compared to			research institute			
Color	Green	Biologi	col	OF. D'. L., 221 01	T / D	ev No.: 2/	(nhtmri) 10 Issue Date: 28	9/02/2024 B	ev Date://	Page 16 of 34
COIGI	Green	Dididgi	cai	QF: Bio Inn.231.01	ISSUE/ R	ev No.: 2/	u – Issue Date: 22	8/U.3/ZUZ4 - R	ev Date://	Page 16 01 34

Indicator Blue

Pharmaceutical Orange **Medical Device** Gray Innovative Herbal Red

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				tace alone in patients with locoregional hepatocellular carcinoma (emerald- 3)			- shifa el orman hospital			
33	Not submitted officially	Cere-cap	Investigato r- initiated	Efficacy of cerebrolysin as an adjuvant therapy following mechanical thrombectomy in patients with large vessels occlusion stroke	Interventional	III	Neurology and psychiatry department, ain shams university hospital	Terminated (by eda) (15/1/2024)	Occlusion stroke	(biological) Cerebrolysin solution for im or iv injection/ concentrate for solution for i.v. infusion
34	14/12/2023	3cd-178	Sponsor: jsc biocad Cro: dataclin	A double-blind, randomized clinical study of the efficacy and safety of bcd-178 and perjeta® as neoadjuvant therapy of her2-positive breast cancer	Interventional	III	-faculty of medicine, aleandria university -faculty of medicine , cairo university	Approved: 22/4/2024	Her-2 positive breast cancer	Biological Bcd-178
35	8/1/2024	Serpinpc 102	Sponsor: apcintex Cro: mct	A global, open- label, adaptive design study to investigate the efficacy and safety of serpinpc in subjects with severe hemophilia a or moderately severe to severe hemophilia b	Interventional	IIB	Ain shams university medical research institute (masri)	Approved 13/6/2024	Hemophilia a or moderately severe to severe hemophilia b	Biological Serpinpc 102

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Blue	Pharmaceutical
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			ı	1		1				
				(ap-0102)						
36	8/1/2024	Serpinpc103	Sponsor: apcintex Cro: mct	A global, open-label study to investigate the efficacy and safety of serpinpc in subjects with hemophilia b with inhibitors (ap-0103)	Interventional	IIB	Ain shams university medical research institute (masri)	Approved 13/6/2024	Hemophilia b with inhibitors	Biological Serpinpc 103
37	17/12/2020	Cega230b2 404	Sponsor: novartis Cro: mct	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, pediatric hepatology unit. 2-alexandria university, faculty of medicine, clinical research center.	Approved 12/4/2021 Recruiting	Fascioliasis	(pharmaceutical) Triclabandazole (egaten)
38	22/12/2020	Clee011a3 201c Right choice	Sponsor: novartis Cro: mct	A phase ii randomized study of the combination of ribociclib plus goserelin acetate with hormonal therapy versus physician choice chemotherapy in premenopausal or	Interventional	II	1-ain shams university, faculty of medicine, clinical research center, (masri – crc) 2-baheya hospital research center 3-cairo university, nemrock 4-nasser institute	Approved 14/10/2021 Completed 8/1/2023	Her-2 negative breast cancer	(pharmaceutical) Ribociclib plus goserelin / physician choice chemotherapy

Color Indicator

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Blue Pharmaceutical
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				perimenopausal patients with hormone receptor- positive/her2- negative inoperable locally advanced or metastatic breast cancer - right choice study			cancer center			
39	24/10/2021	M14-430	Sponsor: abbvie Cro: na	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 completed the studies m14-431 or m14-433	Interventional	III	1-air force specialized hospital 2-national liver institute menoufiya university 3-alexandria university, faculty of medicine, clinical research center. 4-ain shams university, faculty of medicine, clinical research center (masri-crc).	Approved 7/7/2022 Recruitment completion	Chron's disease	(pharmaceutical) Upadacitinib/ matching placebo
40	26/10/2021	Bo40336 Alina	Sponsor: roche Cro: na	A phase iii, open- label, randomized study to evaluate the efficacy and safety of adjuvant alectinib versus adjuvant platinum-based chemotherapy in patients with	Interventional	III	l- cairo university, kasr al eini, center of radiation oncology and nuclear medicine.	Approved 16/3/2022 Recruitment completion	Lung cancer	(pharmaceutical) Alectinib / platinum based chemotherapy

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_											
					completely resected						
					stage ib (tumors ≥ 4						
					cm) to stage iiia						
					anaplastic						
					lymphoma kinase-						
					positive non-small-						
4	41	12/12/2021	Cl_tr_1712	Sponsor:	A multicenter,	Interventional	IV	1- Alexandria		Treatment of	(pharmaceutical)
			2019	eva pharma	interventional, two-			university hospital,	Approved	symptomatic	
			Miracle-ala	Cro: marc	arm, parallel-group,			diabetes,	12/10/2022	diabetic	Alpha-lipoic acid
					randomized, double- blinded, placebo-			metabolism, and lipidology unit,	Recruiting	polyneuropath	(thiotacid)/ matching placebo
					controlled, phase iv			department of	Recruiting	У	matching placebo
					trial to evaluate the			internal medicine.			
					efficacy of alpha-			2- Ain shams			
					lipoic acid in the			university hospital			
					treatment of patients			3- Menoufiya			
					with symptomatic			university hospital			
					diabetic			4- Mansoura			
					polyneuropathy in			university, intrinsic specialized			
					egypt			hospital.			
								5- Beni-suef			
								university hospital,			
								diabetes and			
								endocrinology unit			
4	12	12/12/2021	Mk4482-	Sponsor:	A phase 3	Interventional	III	1-ain shams	A 1	Prophylaxis of	(pharmaceutical)
			013 Move-	msd Cro: na	multicenter, randomized, double			university clinical research center	Approved 18/1/2022	covid-19	Molnunirovin/
			ahead	CIO. Ila	blind, placebo			(masri-crc).	10/1/2022		Molnupiravir/ matching placebo
			ancad		controlled study to			2-air force			matering pracedo
					evaluate the efficacy			specialized hospital.	Completed		
					,				<u>.</u>		

Color Indicator

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				and safety of mk- 4482 for the prevention of covid- 19 (laboratory confirmed sars-cov 2 infection with symptoms) in adults.			3-national hepatology and tropical medicine research institute. 4-imbaba fever hospital. 5-national center for allergies and chest imbaba	16/11/2022		
43	30/3/2022	Gbt440- 032	Sponsor: gbt (subsidiary of pfizer) Cro: cti	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- al mounira children hospital, cairo university, 4-zagazig university hospital, department of pediatrics.	Approved 31/7/2022 Recruitment completion	Sickle cell disease	(pharmaceutical) Voxelotor/ Matching placebo
44	18/4/2022	Gbt440- 034	Sponsor: gbt (subsidiary of pfizer) Cro: iqvia	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	Approved 2/8/2022 Recruitment completion	Sickle cell disease	(pharmaceutical) Voxelotor

Color Indicator

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							hospital, department of pediatrics.			
45	17/5/2022	F901318/0 032	Sponsor: f2g Cro: iqvia	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 (by sponsor) 24/7/2022	Invasive fungal infection	(pharmaceutical) Olorofim
46	12/6/2022	Clsyn.1702 (oasis-9)	Sponsor: hamilton health science Cro: clinmax	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 Recruitment completion	Stemi/non- stemi myocardial infarction	(pharmaceutical) Colchicine, spironolactone/ Matching placebo

Color Indicator

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47	15/6/2022	20140106	Sponsor: onyx pharmaceut icals (subsidiary of amgen) Cro: iqvia	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	Approved 23/8/2022 Withdrawn 19/6/2023	Relapsed or refractory acute lymphoplastic leukemia	(pharmaceutical) Carfilzomib
48	18/7/2022	Ag348-c- 020	Sponsor: Agios Cro: mct	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
49	26/7/2022	F901318/0 041	Sponsor: f2g Cro: iqvia	A phase iii, adjudicator-blinded, randomised study to evaluate the efficacy and safety of treatment with olorofim versus treatment with ambisome®	Interventional	III	1-mansoura university oncology center 2-alexandria university clinical research center 3-air force specialized hospital 4-ain shams	Approved 11/10/2022	Invasive fungal disease caused by aspergillus species	(pharmaceutical) Olorofim / ambisome

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50	27/7/2022	Apd334- 202	Sponsor: arena pharmaceut icals (subsidiary of pfizer)	followed by standard of care (soc) in patients with invasive fungal disease (ifd) caused by aspergillus species A multicenter 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	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 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	Approved 23/8/2022 Recruiting	Moderately to severe active crohn's disease	(pharmaceutical) Etrasimod / matching placebo
				crohn's disease			(nhtmri) 4-cairo university			

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51	7/8/2022	Efc17215 Leap-2- mono	Sponsor: sanofi Cro: na	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 (gd3) who have reached therapeutic goals with enzyme replacement therapy	Interventional	III	1-alexandria university hospital clinical research center	Approved 24/10/2022	Gaucher disease type 3 (gd3)	(pharmaceutical) Venglustat/ cerezyme
52	15/8/2022	Ag348-c- 017	Sponsor: agios Cro: mct	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
53	15/8/2022	Ag348-c- 018	Sponsor: agios Cro: mct	A phase 3, double- blind, randomized, placebo-controlled,	Interventional	III	1-cairo university hospital	Approved 2/11/2022	Transfusion- dependent alpha or beta	(pharmaceutical) Mitapivat /

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				multicenter study 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	Withdrawn 26/6/2023	thalassemia	Matching placebo
54	29/8/2022	4202-hem- 301	Sponsor: forma therapeutic s Cro: mct	An adaptive, randomized, placebo-controlled, double-blind, multicenter study of oral etavopivat, a pyruvate kinase activator in patients with sickle cell disease	Interventional	Ш	1- alexandria university clinical research center 2-zagazig university hospital 3-cairo university hospital 4-ain shams university clinical research center (masri-cre)	Approved 11/12/2022	Sickle cell disease	(pharmaceutical) Etavopivat / matching placebo
55	29/9/2022	Go42784 lidera	Sponsor: roche Cro: mct	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	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	Approved 4/12/2022 Recruitment completion	Estrogen receptor—posit ive, her2- negative early breast cancer	(pharmaceutical) Giredestrant / physician choice of adjuvant endocrine monotherapy

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				estrogen receptor—positive, her2-negative early breast cancer			6- dar el salam cancer hospital 7- sohag oncology center			
56	16/11/2022	(activ- 2d/a5407)	Sponsor: Shionogi Cro: Iqvia	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
57	28/11/2022	Rbsc2161	Sponsor: salix pharmaceut icals Cro: Iqvia	A phase 2a randomized, double-blind, placebo-controlled study to characterize the pharmacokinetics and pharmacodynamics of rifaximin novel formulations in	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	Approved 5/2/2023 Withdrawn 6/11/2023	Sickle cell disease	(pharmaceutical) Rifaximin / matching placebo

Color Indicator

Green **Biological** Blue **Pharmaceutical** Orange **Medical Device** Gray Innovative Red Herbal

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					patients with sickle cell disease			5-alexandria university clinical research center			
5	8 2	22/1/2023	At/03a-017	Sponsor: Atea pharmaceut i-cals Cro: avicemer	A phase 3 randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of bemnifosbuvir in high-risk outpatients with covid-19	Interventional	III	National -\ hepatology and tropical medicine research institute	Approved: 15/10/2023 Withdrawn 7/4/2024	Covid-19	(pharmaceutical) Bemnifosbuvir/m atching placebo
5	9	13/2/2023	Enrich- af	Sponsor: hamilton health science Cro: clinmax	Edoxaban for intracranial haemorrhage survivors with atrial fibrillation (enrichaf) 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 Recruiting	Atrial fibrillation in patients with previous intracranial haemorrhage	(pharmaceutical) Edoxaban
6	60	13/2/2023	Gbt440-	Sponsor:	An open-label	Interventional	III	1-alexandria	Approved	Sickle cell	(pharmaceutical)

Color Indicator

Green	Biological
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		038	gbt (subsidiary of pfizer)	extension study of voxelotor administered orally to paediatric participants with sickle cell disease who have participated in voxelotor clinical trials			university clinical research center 2- zagazig university hospital 3-cairo university, abu el rich hospital. 4- ain shams university, faculty of medicine crc (masri).	30/3/2023 Recruiting	disease	Voxelotor
61	1/3/2023	Gn41851 Fenhance	Sponsor: roche Cro: na	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 Withdrawn 11/1/2024	Relapsing multiple sclerosis	(pharmaceutical) Fenebrutinib/ teriflunomide/ matching placebo
62	6/3/2023	1305-0023 (fibroneer – ild	Sponsor: boehringer ingelheim Cro: iqvia	A double blind, randomized, placebo-controlled trial evaluating the efficacy and safety of bi 1015550 over at least 52 weeks in patients with	Interventional	III	1-ain shams university clinical research center (masri-crc) 2- alexandria university clinical research center 3- air force	Approved 1/6/2023 Withdrawn 17/1/2024	Progressive fibrosing interstitial lung diseases (pf- ilds)	(pharmaceutical) Bi 1015550 / matching placebo

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				progressive fibrosing interstitial lung diseases (pf- ilds)			specialized hospital 4- cairo university, kasr al aini hospital			
63	6/3/2023	1305-0014 (fibroneer – ipf)	Sponsor: boehringer ingelheim Cro: iqvia	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 Withdrawn 08/01/2024	Idiopathic pulmonary fibrosis (ipf)	(pharmaceutical) Bi 1015550 / matching placebo
64	16/3/2023	4202-hem- 201	Sponsor: forma therapeutics Cro: mct	A phase 2 open- label study to evaluate safety and clinical activity of ft-4202 in patients with thalassemia or sickle cell disease	Interventional	П	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
65	15/5/2023	Efc16035 (perseus)	Sponsor: sanofi Cro: na	A phase 3, randomized, double-blind, efficacy and Safety study comparing sar442168 to placebo in Participants with primary progressive multiple	Interventional	III	Alexandria university clinical research center	Approved 10/8/2023 Withdrawn 15/4/2024	Primary progressive multiple Sclerosis	(pharmaceutical) Tolebrutinib/ matching placebo

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				Sclerosis						
66	14/3/2024	Wo43571 heredera	Sponsor: roche Cro: na	A phase iii, randomized, open-label study evaluating the efficacy and safety of giredestrant in combination with phesgo versus phesgo after induction therapy with phesgo+ taxane in patients with previously untreated her2-positive, estrogen receptor-positive locally-advanced or metastatic breast cancer	Interventional	Ш	11- sohag oncology center 2- dar el salam cancer hospital 3- national cancer institute	Approved 8/4/2024	Previously untreated her2-positive, estrogen receptor-positive locally-advanced or metastatic breast cancer	Pharmaceutical Giredestrant
67	24/7/2022	Md-004	Sponsor: ezz medical industries Cro:datacli n	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 Suspended 1-1-2024 Resuming (ongoing) 13/1/2024	Hospitalized mechanically ventilated patients	Medical device (ezvent)

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		1								
68	15/5/2022	Coav101b1 2301	Sponsor: novartis Cro: Mct	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	Interventional	III	1-department of neurology, ain shams university specialized hospital.	Approved 2-8-2022 Early terminated (by sponsor) 18-12-2023	Type 2 spinal muscular atrophy (sma)	Innovative Qav101 (zolgensma) (onasemnogene abeparvovec)
				of age, treatment naïve sitting and						
69	6/6/2023	Urso-003	Sponsor: Minapharm Cro: Nagy research	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	Clinical research center, air force specialized hospital	Approved 18-9-2023 Recruiting	Compensated chronic liver disease patients	Innovative Ursoplus® capsules/ ursofalk® capsules
70	6/6/2023	Cipro-001	Sponsor: Minapharm , Cro:	Single center, open label, controlled study to assess the safety & efficacy of oral ciprodiazole ®	Interventional	IV	1- general syrgery department, menoufia university hospital.	Suspended 12-9-2023	Pelvi- abdominal infections and following iv antibiotics in	Innovative Ciprodiazole ® tablets (ciprofolxacin/

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			Nagy research	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					post-operative period, for pelvi- abdominal surgeries or acute conditions	Metronidazole)
71	15/5/2023	Sub- thromb- 001	Sponsor: Minapharm Cro: na	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	1- department of orthopedics and trauma surgery, elhadra university hospital	Withdrawal 28-8-2023	Prophylaxis of deep vein thrombosis (dvt) post major orthopedic operations	Innovative Thrombex (recombinant hirudin)
72	24/10/2023	Grc/ne- cv/eg/39/iv	Sponsor: Nerhadou internatio-	A prospective, multicentre, open- label, single-arm	Interventional	IV	1- department of general internal medicine	Approved 10-3-2024	Essential hypertension	Innovative Nerkardou

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	nal	interventional study	, beni-suef		(bisoprolol)
		of bisoprolol	university hospital		Oral dispersible
	Cro:	(nerkardou)			film
	Genuine	(between low dose	2- department of		
	research	and high dose) 5 and	cardiology and		
	center	10 mg odf treatment	vascular medicine,		
		in egyptian patients	fayoum university		
		with essential	hospital		
		hypertension			

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