

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OGOS 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BE.798/EQL/2023	Kajian BE	Bisoprolol Fumarate Tablet 5mg	PT Equilab International	LULUS
2.	BX-BE23-AMP-003	Kajian BE	Cynpamax Film Coated Tablet 100mg	Clinical Research Ward, Hospital Ampang	LULUS
3.	C1B03281	Kajian BE	Deferiprone Tablets 500 mg	Cliantha Research Limited	LULUS
4.	D7000C00001	Fasa I/III	AZD3152 150mg/mL, 2mL labelled vial	(a) Hospital Umum Sarawak	LULUS
			AZD1061 100mg/mL, 1.5mL labelled vial	(b) Hospital Seberang Jaya	
			AZD8895 100mg/mL, 1.5mL labelled vial	(c) Pusat Perubatan Universiti Kebangsaan Malaysia (d) University Malaya Medical Centre (e) Sunway Medical Centre	
5.	CHK01-03	Fasa II	Atrasentan Tablet 0.75mg	(a) University Malaya Medical Centre	LULUS
			Matching Placebo Tablet for Atrasentan 0.75mg	(b) Hospital Raja Permaisuri Bainun	
6.	TO-01C101	Fasa I	TO-O-1001, Ophthalmic Solution, 0.1%	(a) Sarawak General Hospital	LULUS
			TO-O-1001 Placebo, Ophthalmic Solution, 0.1%	(b) Hospital Tengku Ampuan Rahimah	
7.	XL092-304	Fasa III	XL092 Tablet 40 mg	(a) Hospital Kuala Lumpur	LULUS
			XL092 Tablet 60 mg	(b) University Malaya Medical Centre	
			XL092 Tablet 100 mg	(c) Institut Kanser Negara	
			Sunitinib Malate 12.5 mg Capsules		
			Sunitinib Malate 25 mg Capsules		
			Nivolumab Concentrate for Solution for Infusion, 10 mg/mL		

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
8.	MK-8591A-053	Fasa III	MK-8591A 100mg / 0.25mg (MK-1439 100mg + MK-8591 0.25mg) film coated tablet	(a) Sarawak General Hospital (b) Hospital Kuala Lumpur (c) Hospital Selayang (d) Hospital Sultanah Bahiyah (e) Hospital Sungai Buloh (f) Hospital Pulau Pinang (g) University Malaya Medical Centre	LULUS
	Bictegravir 50mg / Emtricitabine 200mg / Tenofovir Alafenamide 25mg film-coated tablet				
	Placebo to MK-8591A 100mg / 0.25mg (MK-1439 100mg + MK-8591 0.25mg) film coated tablet				
	Placebo to Bictegravir 50mg / Emtricitabine 200mg / Tenofovir Alafenamide 25mg film-coated tablet				