

**STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUL 2022**

<b>Bil.</b>	<b>No. Protokol</b>	<b>Fasa Kajian Klinikal</b>	<b>Nama Produk</b>	<b>Pusat Kajian Klinikal</b>	<b>Status Permohonan</b>
1.	BX-BE22-AMP-001	Kajian BE	Gapentin Capsule 300mg	<b>Clinical Site:</b> Clinical Research Ward, Clinical Trial Unit, Hospital Ampang  <b>Bioanalytical Site:</b> Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang	LULUS
2.	0064-22	Kajian BE	Eltrombopag Tablets 75 mg	<b>Clinical Site:</b> Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India  <b>Bioanalytical Site:</b> Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India	LULUS BERSYARAT
3.	0065-22	Kajian BE	Eltrombopag Tablets 75 mg	<b>Clinical Site:</b> Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India	LULUS BERSYARAT

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4.	CVAY736K12301	Fasa III	VAY736 (Ianalumab) 150mg/1ml Solution for Injection In Pre-filled Syringe VAY736 (Ianalumab) Placebo/1ml Solution for Injection In Pre-filled Syringe	a) Hospital Sultanah Nur Zahirah b) Hospital Sibul c) Hospital Kuala Lumpur	LULUS
5.	1346-0012	Fasa III	BI 425809 Film-Coated Tablets 10mg Matching placebo to BI 425809 Film-Coated Tablets 10mg	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Hospital Tuanku Jaáfar d) Hospital Sentosa Kuching e) Hospital Raja Permaisuri Bainun	LULUS
6.	MK-6482-022	Fasa III	Belzutifan (MK-6482) 40mg Tablet Belzutifan (MK-6482) 40mg Tablet Placebo MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial	a) Hospital Umum Sarawak b) Hospital Pulau Pinang c) University Malaya Medical Center	LULUS

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7.	ZWI-ZW25-301	Fasa III	ZW25 300mg Powder for concentrate for solution for infusion	a) Institut Kanser Negara b) Pantai Hospital Kuala Lumpur c) Hospital Pulau Pinang d) Hospital Umum Sarawak e) University Malaya Medical Center	LULUS
			BGB-A317 100mg/10mL Concentrate for solution for infusion		
			Trastuzumab Injection 440mg(20ml)		
8.	D910VC00001	Fasa III	25mL Tremelimumab Concentrate for Solution for Infusion. 20mg/mL (25mg/vial)	a) University Malaya Medical Center b) Institut Kanser Negara c) Pantai Hospital Kuala Lumpur d) Hospital Umum Sarawak e) Hospital Pulau Pinang	LULUS
			10mL Durvalumab (MEDI4736) concentrate for solution for infusion, 50mg/mL (500mg/vial)		