

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OKTOBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	032-22	Kajian BE	Aprepitant Capsule 125mg	Clinical site & Bioanalytical site: Ecron Acunova Limited (Formerly known as Manipal Acunova) IV floor, Sri Shirdi Sai Baba Cancer Hospital & Research Centre, Manipal- 576 104, India.	LULUS
2.	0366-21	Kajian BE	Telmisartan Tablets 80 mg	Clinical site & Bioanalytical site: Lambda Therapeutic Research Ltd. Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India	LULUS
3.	417-201-00007	Fasa III	Sibeprenlimab (VIS649) 200mg/mL solution for injection in 2mL vial Placebo for VIS649 200mg/mL solution for injection	i. Hospital Canselor Tuanku Muhriz UKM ii. University of Malaya Medical Centre iii. Hospital Tengku Ampuan Afzan iv. Hospital Tuanku Ja'afar Seremban v. Hospital Kuala Lumpur vi. Hospital Raja Permaisuri Bainun	LULUS
4.	417-201-00012	Fasa III/IV	Sibeprenlimab (VIS649) 200mg/mL solution for injection in 2mL vial	i. Hospital Canselor Tuanku Muhriz UKM ii. University of Malaya Medical Centre iii. Hospital Tengku Ampuan Afzan	LULUS
5.	NN9838-4609	Fasa III	CagriSema 1.0mg/mL + 0.5mg/mL, Solution for Injection CagriSema 2.0mg/mL + 1.0mg/mL, Solution for Injection	a) Universiti Teknologi Mara b) Hospital Universiti Sains Malaysia c) Hospital Umum Sarawak d) Hospital Melaka	LULUS

			CagriSema 4.0mg/mL + 2.0mg/mL, Solution for Injection	e) Hospital Miri f) Hospital Tuanku Jaafar g) Hospital Putrajaya h) Hospital Canselor Tuanku Muhriz i) Hospital Seri Manjung		
			CagriSema 6.8mg/mL + 3.4mg/mL, Solution for Injection			
			CagriSema 9.6mg/mL + 4.8mg/mL, Solution for Injection			
			Placebo Cagrilintide B and Placebo Semaglutide I			
6.	DZ2019E0001	Fasa I/II	DZD9008 150mg Tablet	a) Hospital Kuala Lumpur b) Hospital Sultan Ismail c) Pusat Perubatan Universiti Malaya	LULUS	
			DZD9008 200mg Tablet			
7.	64281802DNG20 04	Fasa II	JNJ-64281802 200mg Oral Film-coated Tablet	a) Klinik Kesihatan Kuang b) Hospital Taiping c) University Malaya Medical Centre	LULUS	
			JNJ-64281802 50mg Oral Film- coated Tablet			
			Matching Placebo for 200mg JNJ-64281802 Oral Film-coated Tablet			
			Matching Placebo for 50mg JNJ-64281802 Oral Film-coated Tablet			
8.	20210096	Fasa III	Bemarituzumab (AMG 552), 20mg/mL Solution For Injection, 20mL Filled Vial	a) University Malaya Medical Centre b) Hospital Umum Sarawak c) Hospital Kuala Lumpur	LULUS	
			Bemarituzumab (AMG 552), 20mg/mL Matching Placebo Solution For Injection, 20mL Filled Vial			

9.	TCH-306	Fasa III	Lonapegsomatropin 12.1 mg hGH / vial, Powder for Injection	a) Hospital Umum Sarawak	LULUS
			Placebo for Lonapegsomatropin 12.1 mg hGH / vial, Powder for Injection	b) Hospital Putrajaya	
			Norditropin® 5 mg/ 1.5 mL Solution for Injection in Pre-Filled Pen	c) University Malaya Medical Centre	
			Pre-filled Syringe with 1.0 mL of Sterile Water for Injection for Reconstitution of Lonapegsomatropin or Placebo	d) Hospital Universiti Sains Malaysia	
				e) Hospital Pulau Pinang	
				f) Hospital Melaka	