

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JANUARI 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	C1B02419	Kajian BE	Trametinib Tablets 2mg	Clinical Site & Bioanalytical Site: Clantha Research Limited Clantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad- 382210, Gujarat, India	LULUS
2.	HZNP-DAX-203	Fasa II	Daxdilimab 100mg/mL Solution (1mL/vial)	a) University Malaya Medical Centre b) Hospital Serdang	LULUS
3.	CAIN457I2401	Fasa IV	Secukinumab (AIN457) 150 mg/1 mL Solution for Injection in Pre Filled Syringe	a) Sarawak General Hospital b) Hospital Selayang c) University Malaya Medical Centre	LULUS
			Placebo for Secukinumab (AIN457) 150 mg/1 mL Solution for Injection in Pre Filled Syringe		
4.	ARV-1801-001	Fasa II	ARV-1801 300 mg Tablet	a) Hospital Sultanah Bahiyah b) Hospital Pulau Pinang c) Hospital Umum Sarawak	LULUS
			Placebo for ARV-1801 300mg Tablet		
5.	NN7769-4514	Fasa III	NNC0365-3769 B 5.0mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge	a) Hospital Ampang b) Hospital Queen Elizabeth I	LULUS
			NNC0365-3769 B 11.3mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge		
			NNC0365-3769 B 25.0mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge		
			NNC0365-3769 B 57.5mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge		
6.	D9185C00001	Fasa III	Tozorakimab (MEDI3506) 150 mg/mL Solution for Injection	a) Hospital Miri	LULUS
			Placebo for Tozorakimab (MEDI3506) 150 mg/mL Solution for Injection		