

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MAC 2023

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	117-22	Kajian BE	Dabigatran Etexilate Capsules 150 mg	Clinical Site & Bioanalytical Site: VerGo Pharma Research Pvt. Ltd.	LULUS
2.	118-22	Kajian BE	Dabigatran Etexilate Capsules 150 mg	Clinical Site & Bioanalytical Site: VerGo Pharma Research Pvt. Ltd.	LULUS
3.	POD0031/CP/R	Phase II/III	Neuroncell-EX (Allogeneic Mesenchymal Stem Cells), 30 million cells in 1.8mL of cryoprotectants (90% human serum albumin and 10% dimethyl sulfoxide (DMSO)) in a 2.0mL polyethylene (PE) cryovial Placebo (1.8mL sterile normal saline in 2mL cryovial)	Hospital Canselor Tuanku Muhriz UKM	LULUS
4.	78934804CRD2001	Phase IIb	Guselkumab/Golimumab (JNJ-78934804) (100 mg/100 mg) in Pre-filled Syringe with UltraSafe Plus™ Passive Needle Guard (PFS-U) Golimumab 100 mg/1 ml in Pre-filled Syringe with UltraSafe Passive® Delivery System Placebo for Guselkumab 200 mg/2 ml in Pre-filled Syringe with Ultrasafe Plus™ Passive Needle Guard (PFS-U) Placebo for Guselkumab 20 ml Solution in Vial Guselkumab 100 mg/1 ml Solution for Infusion or Injection in Pre-filled Syringe	a) Hospital Pulau Pinang b) Hospital Sultanah Bahiyah c) Hospital Ampang d) Pusat Perubatan Universiti Malaya	LULUS

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			Placebo for Guselkumab 100 mg/1 ml Solution		
5.	VT-001-0070	Phase III	Atacicept 150 mg/mL pre-filled syringes Placebo for Atacicept 150 mg/mL pre-filled syringes Mycophenolate Mofetil 500 mg film-coated Tablet	Hospital Kuala Lumpur	LULUS
6.	JEP-2022-536	Phase IV	Mucosolvan® Injection Solution 15mg/2mL	Hospital Canselor Tuanku Muhriz UKM (HCTM)	LULUS