

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	22-VIN-0537	Kajian BE	Bisoprolol Hovid 5 mg Tablet	Clinical Site & Bioanalytical Site: Veeda Clinical Research Ltd.	LULUS
2.	22-VIN-0538	Kajian BE	Bisoprolol Hovid 10 mg Tablet	Clinical Site & Bioanalytical Site: Veeda Clinical Research Ltd.	LULUS
3.	IK2294-(01) Apixaban	Kajian BE	TAH3311 Oral Dissolving Film (ODF) 5 mg Eliquis 2.5 mg Film-Coated Tablets	Clinical Site: CRC Research Ward, Sarawak General Hospital Heart Centre Bioanalytical Site: Info Kinetics Sdn. Bhd.	LULUS
4.	20210004	Phase III	Tarlatamab (AMG 757) 1mg/vial Tarlatamab (AMG 757) 10mg/vial IV Solution Stabilizer 10mL/vial	a) Hospital Tengku Ampuan Afzan	LULUS
5.	MK-3475-D46	Phase III	MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial Sacituzumab Govitecan 200mg Lyophilized powder for IV infusion	a) Hospital Pulau Pinang b) Beacon Hospital Sdn Bhd c) Hospital Raja Perempuan Zainab II	LULUS
6.	MK-7902-014	Phase III	Lenvatinib 1 mg Capsule Lenvatinib 4 mg Capsule	a) Sarawak General Hospital b) University Malaya Medical Centre c) Hospital Kuala Lumpur	LULUS

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			Lenvatinib 10 mg Capsule MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial		
7.	61186372PANSC2002 (PolyDamas)	Phase I/ II	JNJ-63723283 Lyophilized Product 240 mg (30 mg/mL), in 8 mL vial JNJ-61186372 350 mg (50 mg/mL), 7 mL solution	a) Hospital Umum Sarawak b) University Malaya Medical Centre	LULUS