

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUN 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	23-027	Kajian BE	Sunitinib Malate Capsules, 50 mg	Synapse Labs Pvt. Ltd.	LULUS
2.	GARGN-IJZ-1005	Fasa III	GARGN-IJZ 300 U/mL, Solution for Injection in Cartridge	Profil Institut für Stoffwechselforschung GmbH	LULUS
3.	BE. 775/EQL/2022	Kajian BE	Diclofenac Potassium 50mg (Test 1) Diclofenac Potassium 50mg (Test 2)	CRC Research Ward, Sarawak General Hospital Heart Centre	LULUS
4.	D5162C00052	Fasa II	Amivantamab concentrate for solution for infusion 350mg/vial (50 mg/ml) AZD9291 40mg Film-Coated Tablet AZD9291 80mg Film-Coated Tablet	a) Hospital Pulau Pinang b) Hospital Tengku Ampuan Afzan c) Sarawak General Hospital d) University Malaya Medical Centre e) Hospital Raja Perempuan Zainab II f) Hospital Kuala Lumpur	LULUS
5.	MK-1242-036	Fasa II/III	MK-1242 TABLET 2.5MG MK-1242 TABLET 5.0MG MK-1242 TABLET 10.0MG MK-1242 1MG/ML GRANULES MK-1242 PLACEBO TABLET 2.5MG MK-1242 PLACEBO TABLET 5.0MG MK-1242 PLACEBO TABLET 10.0MG MK-1242 PLACEBO 3G GRANULES	a) University Malaya Medical Centre b) Institut Jantung Negara	LULUS
6.	22153	Fasa III	Aflibercept (Bay 86-5321) 114.3 mg/mL solution for injection in a vial Aflibercept (Bay 86-5321) 40 mg/mL (Eylea®) solution for injection in a vial	a) OasisEye Specialists b) Hospital Selayang c) Hospital Shah Alam d) Hospital Al-Sultan Abdullah	LULUS
7.	CNT01959UCO3004	Fasa III	Guselkumab 200mg Prefilled Syringe, 2.0mL	a) University Malaya Medical Centre	

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			Guselkumab 100 mg Prefilled Syringe, 1.0 mL	b) Hospital Sultanah Aminah c) Hospital Tuanku Jaafar	
			Placebo Guselkumab 100 mg Prefilled Syringes, 2.0 mL	d) Hospital Pulau Pinang e) Hospital Selayang	
			Placebo Guselkumab 100 mg Prefilled Syringes, 1.0 mL	f) Hospital Umum Sarawak	
8.	REGEN-016	Fasa III	Single 10mL vial REACT 100x10 ⁶ cells/mL ±20% Suspension for intrarenal injection	a) International Islamic University Malaysia b) Hospital Putrajaya c) University Malaya Medical Centre	LULUS
9.	GGPM-2021-021	Fasa IV	Ceelin Zinc Plus Syrup 120 ml	Hospital Pakar Kanak-Kanak UKM	LULUS
			Matching Placebo for Ceelin Zinc Plus Syrup 120 ml		
10.	ISIS 678354-CS6	Fasa III	0.8mL ISIS 678354 (Olezarsen) solution for Subcutaneous Injection (100 mg/mL) in vials	a) University of Malaya Medical Center b) Hospital Taiping	LULUS
			0.8mL Placebo solution for Subcutaneous Injection (1.5µg/mL Riboflavin, 0.9% sodium chloride) in vials	c) Hospital Sultanah Bahiyah d) Hospital Pulau Pinang	
11.	20220083	Fasa III	ABP 206 240 MG/24ML (10MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION	a) Hospital Universiti Sains Malaysia b) Hospital Umum Sarawak	LULUS
			OPDIVO® (NIVOLUMAB) US 240 MG/24 ML (10 MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION	c) Universiti Kebangsaan Malaysia Medical Centre d) Hospital Pulau Pinang	
			OPDIVO® (NIVOLUMAB) EU 240 MG/24 ML (10 MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION	e) Hospital Kuala Lumpur f) Institut Kanser Negara	
12.	CLOU064F12301	Fasa III	LOU064 (Remibrutinib) 10mg Film-Coated Tablet	Sarawak General Hospital (Dr. Lim Tzyy Huei)	LULUS
			LOU064 (Remibrutinib) 25mg Film-Coated Tablet		
			Matching Placebo to LOU064 (Remibrutinib) 10mg Film-Coated Tablet		

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			Matching Placebo to LOU064 (Remibrutinib) 25mg Film-Coated Tablet		
13.	MOM-M281-006	Fasa II/III	Nipocalimab 600mg (30mg/mL), 20mL Solution for intravenous infusion Sodium Chloride 0.9%, 100mL solution for Intravenous infusion	a) Hospital Ampang b) Hospital Umum Sarawak c) University Malaya Medical Centre d) Hospital Tengku Ampuan Afzan e) Hospital Sultanah Aminah f) Sunway Medical Centre g) Hospital Queen Elizabeth	LULUS
14.	9785-CL-0123	Fasa II	Enzalutamide 40mg capsule	Sarawak General Hospital	LULUS
15.	70033093STR3001 70033093ACS3003	Fasa III	JNJ-70033093 (Milvexian) 25mg Film-coated Tablets Matching Placebo for JNJ-70033093 (Milvexian) 25mg	<u>70033093STR3001</u> a) Hospital Universiti Sains Malaysia b) Hospital Kuala Lumpur c) Hospital Sungai Buloh d) Pusat Perubatan Universiti Kebangsaan Malaysia <u>70033093ACS3003</u> a) Sarawak Heart Centre b) Hospital Queen Elizabeth II c) Universiti Teknologi MARA d) Hospital Universiti Sains Malaysia e) Hospital Pulau Pinang f) Hospital Miri g) Pusat Perubatan Universiti Kebangsaan Malaysia	LULUS