

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OGOS 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	HIPRA-HH-7	Fasa IIb	COVID-19 Vaccine HIPRA (PHH-1V) Emulsion for Injection, 40µg/0.5 mL in 2 mL vial	a) Hospital Pulau Pinang	LULUS
2.	61186372NSC30 04	Fasa III	JNJ-61186372 co- formulated with rHuPH20, 1600mg (160mg/mL), 10mL Solution	a) University Malaya Medical Centre b) Beacon Hospital Sdn Bhd c) Sunway Medical Centre d) Hospital Umum Sarawak e) Pantai Hospital Kuala Lumpur	LULUS
			JNJ-61186372 co- formulated with rHuPH20, 2240mg (160mg/mL), 14mL Solution		
			JNJ-61186372 350mg (50/mL), 7mL Solution		
			Lazertinib 80mg tablet		
3.	D5671C00006	Fasa IIb/III	1 pre-filled multi-dose pen 2.7 mL Cotadutide (MEDI0382) Solution for injection 1 mg/mL	a) University Malaya Medical Centre b) Pusat Perubatan Universiti Kebangsaan Malaysia c) Hospital Universiti Sains Malaysia d) Subang Jaya Medical Centre e) Pantai Hospital Kuala Lumpur f) Hospital Tuanku Ja'afar	LULUS
			1 pre-filled multi-dose pen 2.7 mL Cotadutide (MEDI0382) Solution for injection 5 mg/mL		
			1 pre-filled multi-dose pen 2.7 mL Cotadutide		

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			(MEDI0382) Solution for injection 1 mg/mL matching Placebo 1 pre-filled multi-dose pen 2.7 mL Cotadutide (MEDI0382) Solution for injection 5 mg/mL matching Placebo		
4.	HREC/20/QCHQ/64068	Fasa III	Erdosteine 300mg Capsule Erdosteine Placebo 300mg Capsule	University Malaysia Medical Centre	LULUS
5.	R3918-PNH-2021	Fasa III	Pozelimab (REGN3918) 200 mg/mL solution, 2.0 mL, vial Cemdisiran (ALN-CC5) 200 mg/mL solution, 0.5 mL in a 2 mL vial Ravulizumab 100mg/mL, 3mL injection for intravenous use, 1 vial per carton	a) Hospital Ampang b) Hospital Tengku Ampuan Afzan c) Queen Elizabeth Hospital	LULUS
6.	MK-7684A-006	Fasa III	MK-7684A 10/10 mg/mL, Solution for Infusion, 20mL vial Durvalumab 50 mg/mL, Concentrate for Solution for Infusion, 2.4mL Vial	a) Hospital Pulau Pinang b) Hospital Kuala Lumpur c) University Malaya Medical Centre	LULUS

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			Carboplatin 10mg/mL, Concentrate for Solution for Infusion, 60ml Vial		
			Paclitaxel 6mg/mL, Concentrate for Solution for Infusion, 16.7ml Vial		
			Etoposide 20 mg/mL, Concentrate for Solution for Infusion, 5ml Vial		
			Cisplatin 1 mg/mL, 50 mL Concentrate for Solution for Infusion		
			Pemetrexed, Lysophilized Powder for Solution for Infusion, 500mg/Vial		