

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OGOS 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	072-21	Kajian BE	Sitagliptin Tablet 100 mg	Clinical and Bioanalytical site: AXIS Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500049, India	LULUS
2.	ARL/21/118	Kajian BE	Rivaroxaban Film-Coated Tablets 10 mg	Clinical Site: Accutest Research Laboratories (I) Pvt. Ltd. 101 to 113 & 201 to 204, 1st and 2nd floor, Synergy Square Complex, Krishna Industrial Estate, BIDC, Gorwa, Vadodara – 390016, India Bioanalytical Site: Accutest Research Laboratories (I) Pvt. Ltd. A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai –400709, Maharashtra, India	LULUS
3.	MK-1654-004	Fasa II/III	a) MK-1654 150mg/ml, Sterile Solution for IM Injection, 0.9ml/vial b) MK-1654 Sterile Saline Placebo (0.9% w/v Sodium Chloride), Solution for IM Injection, 1ml/vial	a) Hospital Sibul b) Hospital Wanita Dan Kanak-Kanak Sabah c) Hospital Seri Manjung d) Hospital Pulau Pinang e) Hospital Raja Perempuan Zainab II f) Hospital Seberang Jaya g) Hospital Taiping	LULUS
4.	CLNP023C12301	Fasa III	a) LNP023 10mg Hard Gelatin Capsule	a) Sarawak General Hospital	LULUS

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			b) LNP023 200 mg hard gelatin capsule	b) Hospital Queen Elizabeth	
5.	CLNP023C12001B	Fasa III	a) LNP023 10mg Hard Gelatin Capsule b) LNP023 200 mg hard gelatin capsule	a) Hospital Queen Elizabeth	LULUS
6.	MOR208C310	Fasa III	a) Tafasitamab 200mg vial, powder for concentrate for solution for infusion b) 10 mg Lenalidomide hard capsules c) Placebo for 10 mg Lenalidomide hard capsules d) 15 mg Lenalidomide hard capsules e) Placebo for 15 mg Lenalidomide hard capsules f) 25 mg Lenalidomide hard capsules g) Placebo for 25 mg Lenalidomide hard capsules	a) Hospital Ampang b) Hospital Umum Sarawak c) Hospital Tengku Ampuan Afzan d) Hospital Pulau Pinang e) Subang Jaya Medical Centre f) Sunway Medical Centre g) University Malaya Medical Centre h) Hospital Raja Permaisuri Bainun i) Hospital Sultanah Bahiyah j) Hospital Sultanah Aminah k) Hospital Taiping l) Hospital Universiti Sains Malaysia	LULUS
7.	CK-301-301	Fasa III	a) CK-301 Injection 300 mg/5 mL (60 mg/mL) vial b) Pemetrexed Alvogen 500 mg vial c) Ribocarbo®-L (carboplatin) 450 mg vial, 10 mg/ml d) CISPLATIN ACCORD, 50mL vial, 1 mg/mL	a) Pusat Perubatan Universiti Kebangsaan Malaysia b) University Malaya Medical Centre c) Hospital Pulau Pinang d) Hospital Raja Perempuan Zainab II e) Beacon Hospital f) Hospital Sultan Ismail	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	EDP 938-102	Fasa II	a) EDP-938 200mg Tablets b) EDP-938 200mg Placebo Tablets	a) Universiti Teknologi Mara, UITM Sungai Buloh Campus b) Sunway Medical Centre Berhad c) Hospital Miri d) Hospital Sultanah Nur Zahirah e) Hospital Tuanku Fauziah	LULUS
9.	ENV-IPF-101	Fasa II	a) ENV-101 (Taladegib) 100mg Tablet b) Placebo for ENV-101 (Taladegib) 100mg Tablet	a) Institut Perubatan Respiratori b) Hospital Raja Perempuan Zainab II c) University Malaya Medical Centre d) Universiti Kebangsaan Malaysia Medical Centre e) UiTM Selayang Campus	LULUS
10.	VIR-2218-1006	Fasa II	a) 1 Single Use Vial of VIR-3434, 300mg/vial b) Vial Containing 0.5mL VIR-2218 at 200mg/mL	a) University Malaya Medical Centre b) Hospital Serdang c) Hospital Selayang	LULUS
11.	C4671002	Fasa II/III	a) PF-07321332 Immediate release (IR) film-coated tablet, 150mg b) Ritonavir Capsule, 100mg c) Matching placebo to PF-07321332 Immediate release (IR) film-coated tablet, 150 mg d) Matching placebo to Ritonavir Capsule, 100mg	a) Klinik Kesihatan Kuang b) Hospital Raja Perempuan Zainab II c) Hospital Miri d) Hospital Taiping e) Hospital Seberang Jaya	LULUS BERSYARAT
12.	C4671005	Fasa II/III	a) PF-07321332 Immediate release (IR) film-coated tablet, 150mg	a) Hospital Miri b) Hospital Taiping	LULUS BERSYARAT

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			<ul style="list-style-type: none"> b) Ritonavir Capsule, 100mg c) Matching placebo to PF-07321332 Immediate release (IR) film-coated tablet, 150 mg d) Matching placebo to Ritonavir Capsule, 100mg 	<ul style="list-style-type: none"> c) Hospital Seberang Jaya d) Hospital Umum Sarawak 	
13.	C4671006	Fasa II/III	<ul style="list-style-type: none"> a) PF-07321332 Immediate release (IR) film-coated tablet, 150mg b) Ritonavir Capsule, 100mg c) Matching placebo to PF-07321332 Immediate release (IR) film-coated tablet, 150 mg d) Matching placebo to Ritonavir Capsule, 100mg 	<ul style="list-style-type: none"> a) Klinik Kesihatan Kuang b) Hospital Raja Perempuan Zainab II c) Hospital Miri d) Klinik Kesihatan Greentown e) Hospital Seberang Jaya 	LULUS BERSYARAT