

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JANUARI 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0284-21	Kajian BE	Conzar Tablet 5mg	Clinical & Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS
2.	PR/BE/21/453	Kajian BE	Vonoprazan Film-Coated Tablets 20 mg	Clinical Site: Raptim Research Pvt. Ltd. A-226, PAP-213 (Clinical Unit), T.T.C. Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India. Bioanalytical Site: Raptim Research Pvt. Ltd., A-242 (Bioanalytical and Biostatistical Unit), T.T.C. Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India.	LULUS
3.	0346-21	Kajian BE	Esomeprazole Delayed-Release Tablets (MUPS) 40 mg	Clinical & Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
4.	0345-21	Kajian BE	Esomeprazole Delayed-Release Tablets (MUPS) 40 mg	Clinical & Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey no. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, Gujarat, India	LULUS
5.	COAV101B12301	Fasa III	a) OAV101 4.0e13 vg/mL solution for intrathecal injection 3 mL fill volume b) Okrido® 6mg/mL Oral Solution (Prednisolone Sodium Phosphate) 20mL fill volume c) Placebo to Okrido® 6mg/mL Oral Solution	a) University of Malaya Medical Centre b) Hospital Tunku Azizah	LULUS
6.	IK2224-(01) APai	Fasa I	HEMPEDU BUMI Capsule 200 mg	Info Kinetics Sdn. Bhd.	LULUS
7.	CCSB-CT-PF-01-2021	Fasa I	PF2020-CELL (Allogeneic Umbilical Cord Mesenchymal Stem Cells), 25 million cells in 1.8mL of cryoprotectants (90% human albumin serum and 10% dimethyl sulfoxide (DMSO) in a 2.0 mL polyethylene (PE) vial	University of Malaya Medical Centre	LULUS
8.	MK-1654-007	Fasa III	a) MK-1654 150mg/mL, 0.7mL Dose Sterile Solution for Injection/Vial b) Palivizumab 100mg/mL, 1mL Solution for Injection/Vial c) MK-1654 Sterile Saline Placebo (0.9% w/v Sodium Chloride), 0.7mL Dose Sterile Solution for Injection/Vial	a) Hospital Sibul b) Hospital Raja Perempuan Zainab II c) Sabah Women and Children's Hospital (Likas Hospital) d) Hospital Tunku Azizah (Hospital Wanita and Kanak-Kanak Kuala Lumpur) e) Hospital Pulau Pinang f) University of Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
9.	ANB019-301	Fasa III	a) Imsidolimab (ANB019) 100 mg/mL, 1mL per vial b) Placebo for Imsidolimab (ANB019) 100mg/mL vial, 1mL per vial	a) Universiti Kebangsaan Malaysia Medical Centre b) Hospital Kuala Lumpur c) Hospital Putrajaya d) Hospital Pakar Sultanah Fatimah e) Hospital Sultanah Aminah f) Hospital Raja Perempuan Zainab II	LULUS
10.	ANB019-302	Fasa III	a) Imsidolimab (ANB019) 100 mg/mL, 1mL per vial b) Placebo for Imsidolimab (ANB019) 100mg/mL vial, 1mL per vial	a) Universiti Kebangsaan Malaysia Medical Centre b) Hospital Kuala Lumpur c) Hospital Putrajaya d) Hospital Pakar Sultanah Fatimah e) Hospital Sultanah Aminah f) Hospital Raja Perempuan Zainab II	LULUS
11.	KBP5074-3-001	Fasa III	a) KBP-5074 Tablets 0.25 mg b) KBP-5074 Tablets 0.50 mg c) Matching Placebo for KBP-5074 0.25 mg or 0.5 mg Tablet	a) Hospital Raja Permaisuri Bainun b) Hospital Raja Perempuan Zainab II c) University Malaya Medical Centre d) Hospital Seri Manjung	LULUS
12.	MK-3655-001	Fasa III	a) MK-3655 33.3mg/mL, Solution for Injection, 1.5mL/vial b) MK-3655 100mg/mL, Solution for Injection, 1.5mL/vial c) MK-3655 Placebo, Solution for Injection, 1.5mL/vial	Hospital Kuala Lumpur	LULUS
13.	1378-0005	Fasa II	a) BI 690517 film-coated tablets 3 mg b) BI 690517 film-coated tablets 10 mg	a) Thomson Hospital Kota Damansara	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			c) Empagliflozin film-coated tablets 10mg d) Matching placebo to BI 690517 film-coated tablets 3 mg e) Matching placebo to BI 690517 film-coated tablets 10 mg f) Matching placebo to Empagliflozin film-coated tablets 10mg g) Synacthen® (Tetracosactide hexa-acetate) Solution for Injection 250 µg/ 1mL ampoule	b) Universiti Kebangsaan Malaysia Medical Centre (PPUKM) c) Hospital Raja Perempuan Zainab II	