

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2021

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0284-19	Kajian BE	Olanzapine Orodispersible Tablet 5mg	Clinical and 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.	MES/2020/1791 MES/2020/1792	Kajian BE	Mesalamine Extended-Release Capsules USP, 500mg	Clinical site: Synchron Research Services Pvt Ltd Clinical Department, 201 & 301, 2nd & 3rd Floor, Satva, Opp Bhavin School, Thaltej, Ahmedabad 380059 Gujarat, India. Bioanalytical site: "Synchron House", Behind Mondeal Park, Near Gurudwara, S.G. Highway, Ahmedabad – 380059, Gujarat, India	LULUS
3.	1366-0022 1366-0005	Fasa II	a) BI 685509 film-coated tablets 1 mg b) BI 685509 film-coated tablets 2 mg c) BI 685509 film-coated tablets 3 mg d) Matching placebo to BI 685509 film-coated tablets 1 mg e) Matching placebo to BI 685509 film-coated tablets 2 mg f) Matching placebo to BI 685509 film-coated tablets 3 mg	a. Hospital Raja Permaisuri Bainun b. University Malaya Medical Centre c. University Kebangsaan Malaysia Medical Centre d. Hospital Selayang,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
4.	POD0030/CP/R	Fasa I/II	Cyto-MSC (Allogeneic Mesenchymal Stem Cells), 25 million cells in 1.8ml of cryoprotectants (90% human serum and 10% dimethyl sulfoxide (DMSO)) in a 2.0ml polyethylene (PE) cryovial	<ul style="list-style-type: none"> a. Hospital Ampang b. Sunway Medical Centre c. Hospital Canselor Tuanku Muhriz UKM 	LULUS
5.	2021L001	Fasa III	<ul style="list-style-type: none"> a) SARS-CoV-2 Vaccine (Vero Cells), Inactivated, 5µg/0.5ml b) Placebo of SARS-CoV-2 Vaccine (Vero Cells), Inactivated 	<ul style="list-style-type: none"> a) Alps Medical Centre b) Clinique Healthy Malaysia c) Columbia Asia Hospital, Klang d) Columbia Asia Hospital, Bukit Rimau e) Life Care Diagnostic Medical Centre f) Sri Kota Specialist Medical Centre g) Nilai Medical Centre 	LULUS