

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2021

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	PRO-nCOV-3002	Fasa III	a) Inactivated SARS-CoV-2 virus 600SU/0.5ml pre-filled syringe b) Matching placebo for inactivated SARS-CoV-2 virus 600SU/0.5ml pre-filled syringe	a) Hospital Sibu b) Klinik Kesihatan Cheras Baru c) Hospital Miri d) Hospital Seberang Jaya e) Hospital Raja Permaisuri Bainun f) Hospital Wanita dan Kanak-Kanak Sabah g) Hospital Sungai Buloh h) University Malaya Medical Centre i) Hospital Pengajar UiTM Puncak Alam	LULUS
2.	JSVCT109	Fasa III	a) Recombinant COVID-19 vaccine (Sf9 Cells), 40µg/1.0 mL/vial Suspension for Injection b) Placebo for Recombinant COVID-19 vaccine (Sf9 Cells), 1.0 mL/vial Suspension for Injection	a) Klinik Kesihatan Pandamaran	LULUS
3.	ARCoV-005	Fasa III	a) SARS-CoV-2 mRNA Vaccine, Injection, 0.5mL/syringe, containing 15µg of mRNA b) Placebo for SARS-CoV-2 mRNA Vaccine, Injection, 0.5mL/syringe, containing 15µg of mRNA	a) Hospital Seberang Jaya b) Hospital Ampang c) Klinik Kesihatan Greentown	LULUS
4.	BX-BE21-AMP-001 BX-BE21-AMP-002	Kajian BE	Dulotine Enteric Microencapsulated Capsule 60mg	Clinical Site: Clinical Research Ward Level 7, Hospital Ampang,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				<p>Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p>Bioanalytical Site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	
5.	026-20	Kajian BE	Etoricoxib Tablets 120 mg	<p>Clinical Site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p> <p>Bioanalytical Site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p>	LULUS
6.	MI-21-rivaroxaban-06	Kajian BE	Rivaroxaban Film-coated Tablets 20mg	<p>Clinical Site: Siriraj Institute of Clinical Research (SICRES) 10th floor, Siriraj Medical Research Center (SiMR) Faculty of Medicine Siriraj Hospital, Mahidol University</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				<p>2 Wanglang Road, Siriraj, Bangkoknoi, Bangkok 10700, Thailand</p> <p>Bioanalytical Site: Medica Innova Co. Ltd. 5-7th Floor, 147 Soi Sabaijai, Suthisarnwinichai Road, Bangkok 10310, Thailand</p>	
7.	PR/BE/21/305	Kajian BE	Dapagliflozin Tablets 10 mg	<p>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</p> <p>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.</p>	LULUS
8.	040-21	Kajian BE	Ezetimibe and Simvastatin Tablets 10 mg/10 mg	<p>Clinical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27,</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				<p>Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p> <p>Bioanalytical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p>	
9.	041-21	Kajian BE	Ezetimibe and Simvastatin Tablets 10 mg/40 mg	<p>Clinical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p> <p>Bioanalytical Site: RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India</p>	LULUS
10.	SIR365-AU-102	Fasa Ib	<p>a) SIR1-365 tablets 100 mg</p> <p>b) Matching Placebo for SIR1-365 tablets 100 mg</p>	<p>a) Subang Jaya medical Centre</p> <p>b) Hospital Kuala Lumpur</p> <p>c) Hospital Selayang</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				d) University Malaya Medical Centre e) Oriental Melaka straits Medical Centre f) Sunway Medical Centre	
11.	A4250-012	Fasa III	a) Odevixibat (A4250) 200mcg Capsules b) Odevixibat (A4250) 600mcg Capsules c) Odevixibat (A4250) 400mcg Capsules d) Odevixibat (A4250) 1200mcg Capsules e) Placebo to match Odevixibat (A4250) 200mcg or 600mcg f) Placebo to match Odevixibat (A4250) 400mcg or 1200mcg	a) University of Malaya Medical Centre	LULUS
12.	CBYL719K12301	Fasa III	a) Olaparib 100mg Film-Coated Tablet b) Olaparib 150mg Film-Coated Tablet c) BYL719 (Alpelisib) 50 mg Film-Coated Tablet d) BYL719 (Alpelisib) 200 mg Film-Coated Tablet	a) Hospital Wanita Dan Kanak-Kanak Sabah b) Hospital Kuala Lumpur a) Universiti Malaya Medical Centre	LULUS
13.	EX6018-4758	Fasa III	a) Ziltivekimab B 15mg/mL 1X1mL Prefilled Syringe b) Placebo 1 X 1mL Prefilled Syringe	a) Hospital Universiti Sains Malaysia b) Sarawak Heart Centre c) Hospital Raja Perempuan Zainab II d) University Malaya Medical Centre e) Institute Jantung Negara f) Hospital Queen Elizabeth II g) University Technology MARA h) Hospital Tuanku Ja'afar i) Hospital Sultanah Bahiyah	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
14.	67896049PAH4005	Fasa IV	a) Tablet Selexipag 200µg (140tabs/bottle) b) Tablet Selexipag 200µg (60tabs/bottle) c) Tablet Selexipag 400µg (60tabs/bottle) d) Tablet Selexipag 400µg (60tabs/bottle) e) Tablet Selexipag 600µg (60tabs/bottle) f) Tablet Selexipag 800µg (60tabs/bottle) g) Tablet Selexipag 1000µg (60tabs/bottle) h) Tablet Selexipag 1200µg (60tabs/bottle) i) Tablet Selexipag 1400µg (60tabs/bottle) j) Tablet Selexipag 1600µg (60tabs/bottle)	a) Institut Jantung Negara	LULUS
15.	MO42541	Fasa III	a) Atezolizumab 1200mg/20ml, concentrate for solution for IV infusion b) Lenvatinib 4mg hard capsules	a) Institut Kanser Negara b) Beacon Hospital Sdn. Bhd. c) University Malaya Medical Centre	LULUS
16.	R3918-PNH-2092	Fasa II	a) Pozelimab, Solution for Injection, 200 mg/mL, supplied in 6R glass vial b) Cemdisiran, Solution for Injection, 200 mg/mL, supplied in 2 mL glass vial	a) Hospital Miri b) Hospital Sultanah Nur Zahirah c) Hospital Sibul	LULUS
17.	Kod NN21-40	Fasa III	a) AB-LIFETM Probiotic for Intestinal Health Lactobacillus Plantarum CECT7527, CECT7528 and CECT7529 at total 1.2 billion CFU/cap b) AB-LIFETM Probiotic for Intestinal Health (Placebo) Lactobacillus Plantarum CECT7527, CECT7528 and CECT7529 at total 1.2 billion CFU/cap	a) Endocrine Clinic of Pusat Perubatan Universiti Kebangsaan Malaysia	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
18.	VT-001-005	Fasa IIb	a) 1mL of 25 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection b) 1mL of 75 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection c) 1 mL of 150 mg/mL Atacicept Solution in Prefilled Syringe for Subcutaneous Injection d) 1 mL of Placebo Solution in Prefilled Syringe for Subcutaneous Injection	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Hospital Tengku Ampuan Afzan d) Hospital Taiping	LULUS