

**STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MAC 2022**

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	049-20	Kajian BE	a) Ezetimibe Tablet 10mg (Test 1) b) Ezetimibe Tablet 10mg (Test 2)	Clinical site & Bioanalytical site: RA Chem Pharma Limited, Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
2.	078-21	Kajian BE	Sacubitril and Valsartan Tablets 24 mg/26 mg	Clinical site & Bioanalytical site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
3.	079-21	Kajian BE	Sacubitril and Valsartan Tablets 97 mg/103 mg	Clinical site & Bioanalytical site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
4.	0453-21	Kajian BE	Gefitinib Tablets 250 mg	Clinical site & Bioanalytical site: Lambda Therapeutic Research Ltd, India Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS
5.	0457-21	Kajian BE	Pazopanib Tablets 400mg	Clinical site & Bioanalytical site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota,	LULUS

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				Ahmedabad – 382481, Gujarat, India	
6.	BX-BE21-AMP-006	Kajian BE	Amipride Tablets 400mg	<p>Clinical site: Clinical Research Ward (CRW) Level 7, Hospital Ampang, 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, Pulau Pinang</p>	LULUS
7.	226688	Fasa II/III	80mg (10mg/ml) of PRL3-zumab in 8.0 mL solution per vial	<p>a) Hospital Kuala Lumpur b) Hospital Pulau Pinang</p>	LULUS
8.	AT-02A-002	Fasa II	<p>a) AT-752 250 mg tablet b) AT-752 250 mg placebo tablet</p>	<p>a) Hospital Seberang Jaya b) Hospital Sultanah Nur Zahirah</p>	LULUS
9.	F901318/0041	Fasa III	<p>a) 30mg Olorofim film-coated tablet b) 50mg AmBisome®, Liposomal Amphotericin B Powder for dispersion for infusion</p>	<p>a) Hospital Ampang b) University Malaya Medical Centre</p>	LULUS
10.	CAIN457A02001B	Fasa IV	<p>a) Secukinumab (AIN457) 150 mg/1 mL Solution for injection in pre-filled syringe b) Secukinumab (AIN457) 75 mg/0.5 mL Solution for injection in pre-filled syringe</p>	<p>a) Hospital Umum Sarawak b) University Malaya Medical Centre</p>	LULUS
11.	D967YC00001	Fasa Ib	a) DS-8201a Powder for concentrate for solution for infusion 100mg/vial	<p>a) Hospital Umum Sarawak b) Institut Kanser Negara c) University Malaya Medical Centre d) Hospital Pulau Pinang</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			b) 10mL Durvalumab (MEDI4736) Concentrate for solution for infusion, 50mg/mL (500mg/vial)		
12.	CHDM201112201	Fasa Ib/II	a) Siremadlin (HDM201) 10mg Hard Gelatin Capsule b) Siremadlin (HDM201) 20mg Hard Gelatin Capsule c) Venetoclax 10mg Film-coated Tablet d) Venetoclax 50mg Film-coated Tablet e) Venetoclax 100mg Film-coated Tablet	a) Hospital Ampang b) Hospital Sultanah Bahiyah c) University Malaya Medical Centre	LULUS
13.	VIT-2763-THAL-203	Fasa Ib	a) VIT-2763 60mg capsule b) VIT-2763 30mg capsule c) Placebo to VIT-2763 60mg or 30mg capsule	a) University Malaya Medical Centre b) Hospital Sultanah Bahiyah c) Hospital Sultanah Aminah d) Hospital Umum Sarawak e) Hospital Ampang	LULUS