

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN DISEMBER 2020

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	IK0380-(09) Cefuroxime	Kajian BE	Altacef (Cefuroxime Axetil Tablets USP) 500 mg	Info Kinetics Sdn Bhd 5th Floor, Gleneagles Penang, No. 1 Jalan Pangkor, 10050 Penang, Malaysia	LULUS
2.	175-20	Kajian BE	Deferasirox Tablet 360mg	AXIS Clinicals Limited 1- 121/1, Miyapur, Hyderabad- 500 049, India.	LULUS
3.	176-20	Kajian BE	Deferasirox Tablet 360mg	AXIS Clinicals Limited 1- 121/1, Miyapur, Hyderabad- 500 049, India.	LULUS
4.	052-20	Kajian BE	Tadalafil Tablets 20mg	RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
5.	053-20	Kajian BE	Tadalafil Tablets 20mg	RA Chem Pharma Ltd, Clinical Research & Biosciences Division (CRBio) Plot No: 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
6.	D7551C00001	Fasa IIb	<ul style="list-style-type: none"> a) AZD5718 10 mg Tablet b) AZD5718 25 mg Tablet c) AZD5718 125 mg Tablet d) Dapagliflozin 10 mg Film-Coated Tablet e) Matching Placebo for AZD5718 10 mg Tablet f) Matching Placebo for AZD5718 25 mg Tablet g) Matching Placebo for AZD5718 125 mg Tablet 	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Klinik Kesihatan Masjid Tanah c) Hospital Sibul d) Universiti Kebangsaan Malaysia Medical Centre e) Hospital Kuala Lumpur f) Klinik Kesihatan Seremban 2 	LULUS
7.	53718678RSV2005	Fasa II	<ul style="list-style-type: none"> a) JNJ-53718678-ZCL, 23 mg/mL, powder containing 1988 mg JNJ-53718678-ZCL for suspension/ bottle b) JNJ-53718678-ZCL Solvent for suspension, 92ml/ bottle c) Placebo to JNJ-53718678-ZCL, 23 mg/mL, placebo powder for suspension/ bottle 	<ul style="list-style-type: none"> a) Hospital Ampang b) Penang General Hospital c) Sunway Medical Centre d) University Malaya Medical Centre 	LULUS
8.	MS200527_0082	Fasa III	<ul style="list-style-type: none"> a) Evobrutinib 45 mg Film-Coated Tablet b) Matching Placebo for Evobrutinib 45 mg Film-Coated Tablet c) Teriflunomide 14 mg Film-Coated Tablet 	<ul style="list-style-type: none"> a) Hospital Kuala Lumpur b) Hospital Umum Sarawak c) Hospital Seberang Jaya d) Pusat Perubatan Universiti Kebangsaan Malaysia e) Hospital Sungai Buloh f) University Malaya Medical Centre 	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			d) Matching Placebo for Teriflunomide 14 mg Film-Coated Tablet		
9.	WN42349	Fasa III	a) Satralizumab 120mg/ 1ml, pre-filled syringe	a) Hospital Kuala Lumpur	LULUS
10.	BO42162	Fasa III	a) Crovalimab 170mg/1mL solution for IV infusion or SC injection b) Soliris (eculizumab) 300mg/30mL (10mg/mL) Solution for Infusion in Vial	a) Hospital Pulau Pinang b) Hospital Tengku Ampuan Afzan c) Hospital Ampang d) Hospital Raja Permaisuri Bainun e) Hospital Universiti Sains Malaysia f) Pusat Perubatan Universiti Kebangsaan Malaysia	LULUS
11.	67652000PCR3002	Fasa III	a) Niraparib 100mg Capsules b) Abiraterone Acetate 250mg Tablets c) CJNJ67652000 50/500mg FDC Tablets d) CJNJ67652000 100/500mg FDC Tablets e) Placebo Niraparib 100mg Capsules f) Placebo Abiraterone Acetate 250mg Tablets g) Placebo CJNJ67652000 50/500MG FDC Tablets	a) Hospital Umum Sarawak b) Hospital Sultan Ismail c) University Malaya Medical Centre d) Hospital Pulau Pinang e) Hospital Kuala Lumpur f) Institut Kanser Negara	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			h) Placebo CJNJ67652000 100/500MG FDC Tablets		
12.	20200404	Fasa III	a) SARS-CoV-2 Vaccine, Inactivated (Vero cell) 150U/0.5ml Suspension For Injection b) Placebo To Match SARS-CoV-2 Vaccine, Inactivated (Vero cell) 150U/0.5ml Suspension For Injection	a) Hospital Ampang b) Hospital Umum Sarawak c) Hospital Pulau Pinang d) Hospital Seberang Jaya e) Hospital Raja Permaisuri Bainun f) Hospital Taiping g) Hospital Sultanah Bahiyah h) Hospital Sungai Buloh i) Hospital Sultan Abdul Halim	LULUS