

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN FEBRUARI 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	RMC-6291-001	Kajian FIH	RMC-6291 Tablets, 25mg RMC-6291 Tablets, 100mg	Clinical Site & Bioanalytical Site: a) Hospital Umum Sarawak	LULUS
2.	SIM0417-301	Fasa II/III	SIM0417 Tablet 375mg Ritonavir Tablet 100mg SIM0417 Placebo Tablet 375mg Ritonavir Placebo Tablet 100mg	a) Klinik Kesihatan Kuala Kedah b) Klinik Kesihatan Mahmoodiah c) ALPS Medical Centre	LULUS
3.	064-22	Kajian BE	Tofacitinib Film-Coated Tablets 5mg	Clinical site & Bioanalytical site: Cohance Lifesciences Ltd Clinical Research & Biosciences Division, Plot-No.26&27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, INDIA	LULUS
4.	0195-22	Kajian BE	Apixaban 5mg Tablet	Clinical site & 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.	PR/BE/22/150	Kajian BE	Proxib 400mg Capsule	Clinical site: Raptim Research Limited A-226, T.T.C., Industrial Area, Mahape M.I.D.C., Navi Mumbai- 400701, India. Bioanalytical site: Raptim Research Limited A-242, T.T.C., Industrial Area, Mahape M.I.D.C., Navi Mumbai- 400701, India.	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
6.	0356-22	Kajian BE	Ezetimibe/Simvastatin Tablet 10mg/20mg	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
7.	19767	Fasa III	Asundexian 50mg Film-Coated Tablet Apixaban 2.5mg film-coated tablet Apixaban 5mg film-coated tablet Placebo film-coated tablet 622 to BAY 2433334 50mg film-coated tablet Placebo coated tablet 251 to Apixaban 2.5mg tablet Placebo coated tablet 502 to Apixaban 5mg tablet	a) University Malaya Medical Centre b) Sarawak Heart Centre c) Sarawak General Hospit d) Hospital Universiti Sains Malaysia e) Hospital Raja Perempuan Zainab II f) Hospital Tuanku Jaafar g) Hospital Tengku Ampuan Afzan h) Pusat Perubatan Universiti Kebangsaan Malaysia (PPUKM) i) Hospital Sultanah Aminah j) Hospital Seberang Jaya k) Hospital Sultanah Bahiyah l) Hospital Serdang m) Universiti Teknologi MARA	LULUS
8.	20604	Fasa III	Asundexian 50mg Film-Coated Tablet Placebo film-coated tablet 622 to BAY 2433334 50mg film-coated tablet	a) University Malaya Medical Centre b) Sarawak General Hospita c) Hospital Seberang Jaya d) Hospital Queen Elizabeth e) Hospital Kuala Lumpur f) Hospital Raja Perempuan Zainab II	LULUS
9.	CVAY736I12301	Fasa III	VAY736 (lanalumab) 150mg/1ml Concentrate for Solution for Infusion Placebo 0mg/1mL for VAY736 (lanalumab) 150mg/1ml Concentrate for Solution for Infusion	a) Sarawak General Hospital b) Hospital Sultanah Aminah c) Hospital Ampang d) Gleneagles Hospital Penang	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
				e) Hospital Canselor Tuanku Muhriz UKM	
10.	CVAY736O12301	Fasa III	VAY736 (lanalumab) 150mg/1ml Concentrate for Solution for Infusion Placebo 0mg/1mL for VAY736 (lanalumab) 150mg/1ml Concentrate for Solution for Infusion	a) Sarawak General Hospital b) Hospital Sultanah Aminah c) Hospital Ampang d) Gleneagles Hospital Penang e) Hospital Canselor Tuanku Muhriz UKM f) Hospital Pulau Pinang	LULUS
11.	CVAY736Q12301	Fasa III	VAY736 (lanalumab) 150mg/1ml Concentrate for Solution for Infusion Placebo 0mg/1mL for VAY736 (lanalumab) 150mg/1ml Concentrate for Solution for Infusion	a) Sarawak General Hospital b) Hospital Sultanah Aminah c) Hospital Ampang d) Gleneagles Hospital Penang e) Hospital Canselor Tuanku Muhriz UKM f) Hospital Pulau Pinang g) Subang Jaya Medical Centre h) Hospital Queen Elizabeth I	LULUS
12.	D9488C00001	Fasa III	Sodium Zirconium Cyclosilicate (SZC) 5 g powder for oral suspension Sodium Zirconium Cyclosilicate (SZC) 10 g powder for oral suspension Placebo for Sodium Zirconium Cyclosilicate (SZC) 5 g powder for oral suspension Placebo for Sodium Zirconium Cyclosilicate (SZC) 10 g Powder for oral suspension	a) Hospital Serdang b) Hospital Sultanah Bahiyah c) University Malaya Medical Centre d) Hospital Kuala Lumpur e) Pusat Perubatan Universiti Kebangsaan Malaysia f) Hospital Selayang g) Hospital Seri Manjung	LULUS