

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN NOVEMBER 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	ARSB-BE-001	Kajian BE	Valsarvid Tablet 320mg Diovan 320mg Forte Film-Coated Tablet	Clinical site & Bioanalytical site: Clinical Research Ward, Clinical Trial Unit Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor, Malaysia	LULUS
2.	BE.741/EQL/2022	Kajian BE	hovid-Clofenac 50 mg Enteric Coated Tablet	Clinical Site: PT Equilab International Jl. RS. Fatmawati Persil 33 Jakarta 12430 – INDONESIA Bioanalytical Site: PT Equilab International Jl. RS. Fatmawati Persil 33 Jakarta 12430 – INDONESIA	LULUS
3.	22-VIN-0268	Kajian BE	Nilotinib Capsules 200mg	Clinical Site: Veeda Clinical Research Pvt. Ltd. 2nd, 3rd & 4th Floor, Shivalik Plaza-A, Near I.I.M., Ambawadi, Ahmedabad, 380015, Gujarat, India.	LULUS

				<p>Bioanalytical Site: Veeda Clinical Research Pvt. Ltd. Rev. Sur. No. 12/1, Insignia, Opposite AUDA Garden, Sindhu Bhavan Road, S. G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India.</p>	
4.	051-22	Kajian BE	Sitagliptin Tablet 100 mg	<p>Clinical Site: VerGo Pharma Research Pvt. Ltd. (Division – VerGo Clinicals), Plot No 24/1, D-1, Mologa de Orora, Corlim, Tiswadi, Goa 403110, India</p> <p>Bioanalytical Site: VerGo Pharma Research Pvt. Ltd. (Division – VerGo Clinicals), Plot No 24/1, D-1, Mologa de Orora, Corlim, Tiswadi, Goa 403110, India</p>	LULUS
5.	1305-0014	Fasa III	<p>BI 1015550 9mg Film-coated tablet BI 1015550 18mg Film-coated tablet Matching Placebo BI 1015550 9mg Film-coated tablet Matching Placebo BI 1015550 18mg Film-coated tablet</p>	<p>a) Hospital Serdang b) Institut Perubatan Respiratori c) Hospital Pulau Pinang d) Hospital Umum Sarawak</p>	LULUS

6.	1305-0023	Fasa III	BI 1015550 9mg Film-coated tablet BI 1015550 18mg Film-coated tablet Matching Placebo BI 1015550 9mg Film-coated tablet Matching Placebo BI 1015550 18mg Film-coated tablet	a) Hospital Serdang b) Institut Perubatan Respiratori c) Hospital Pulau Pinang d) Hospital Umum Sarawak	LULUS
7.	TICH-3	Fasa III	Tranexamic Acid 500mg in 5mL Solution for Injection Sodium Chloride Injection BP 0.9% w/v	a) Pusat Perubatan Universiti Kebangsaan Malaysia b) Hospital Universiti Teknologi Mara	LULUS
8.	R2477-FOP-2175	Fasa III	Garetosmab (REGN2477), 60mg/ml, 5.0ml Liquid In 10.0ml Vial Placebo Product Matching REGN2477, 5.0ml Liquid in 10ml Vial	Hospital Kuala Lumpur	LULUS
9.	54179060MCL3004	Fasa II/III	Ibrutinib 140 mg Oral Capsule Ibrutinib 70 mg Oral Capsule Lenalidomide 2.5 mg Hard Capsules Lenalidomide 5 mg Hard Capsules Lenalidomide 10 mg Hard Capsules Lenalidomide 15 mg Hard Capsules	a) Hospital Ampang b) Hospital Queen Elizabeth c) Hospital Sultanah Aminah d) Universiti Malaya Medical Center e) Subang Jaya Medical Center	LULUS

			<p>Lenalidomide 20 mg Hard Capsules</p> <p>Velcade (Bortezomib) 3.5 mg Powder for Solution for Injection/Infusion</p> <p>Rituximab 500 mg Concentrate for Solution for Infusion</p>		
10.	61186372NSC3005	Fasa III	<p>Osimertinib 40mg Film-coated tablet</p> <p>Osimertinib 80mg Film-coated tablet</p> <p>JNJ-61186372 co-formulated with rHuPH20, 1600mg (160mg/mL), 10mL Solution</p> <p>JNJ-61186372 co-formulated with rHuPH20, 2240mg (160mg/mL), 14mL Solution</p> <p>Lazertinib 80mg tablet</p>	<p>a) University Malaya Medical Centre</p> <p>b) Sunway Medical Centre</p> <p>c) Hospital Kuala Lumpur</p> <p>d) Pantai Hospital Kuala Lumpur</p> <p>e) Hospital Sultanah Bahiyah</p> <p>f) Hospital Sultan Ismail</p> <p>g) Hospital Raja Perempuan Zainab II</p>	LULUS
11.	LYT-100-2022-204	Fasa II	<p>Deupirfenidone (LYT-100) 275mg capsules</p> <p>Placebo for Deupirfenidone (LYT-100) 275mg capsules</p> <p>Pirfenidone 267mg Capsule</p>	<p>a) Institut Perubatan Respiratori</p> <p>b) Universiti Kebangsaan Malaysia Medical Centre</p> <p>c) Hospital Serdang</p> <p>d) Hospital Tengku Ampuan Afzan</p>	LULUS