

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JANUARI 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0284-21	Kajian BE	Conzar Tablet 5mg	Clinical & 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
2.	PR/BE/21/453	Kajian BE	Vonoprazan Film-Coated Tablets 20 mg	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. 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.	LULUS
3.	0346-21	Kajian BE	Esomeprazole Delayed-Release Tablets (MUPS) 40 mg	Clinical & 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

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
4.	0345-21	Kajian BE	Esomeprazole Delayed-Release Tablets (MUPS) 40 mg	Clinical & 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.	COAV101B12301	Fasa III	a) OAV101 4.0e13 vg/mL solution for intrathecal injection 3 mL fill volume b) Okrido® 6mg/mL Oral Solution (Prednisolone Sodium Phosphate) 20mL fill volume c) Placebo to Okrido® 6mg/mL Oral Solution	a) University of Malaya Medical Centre b) Hospital Tunku Azizah	LULUS
6.	IK2224-(01) APai	Fasa I	HEMPEDU BUMI Capsule 200 mg	Info Kinetics Sdn. Bhd.	LULUS
7.	CCSB-CT-PF-01-2021	Fasa I	PF2020-CELL (Allogeneic Umbilical Cord Mesenchymal Stem Cells), 25 million cells in 1.8mL of cryoprotectants (90% human albumin serum and 10% dimethyl sulfoxide (DMSO) in a 2.0 mL polyethylene (PE) vial	University of Malaya Medical Centre	LULUS
8.	MK-1654-007	Fasa III	a) MK-1654 150mg/mL, 0.7mL Dose Sterile Solution for Injection/Vial b) Palivizumab 100mg/mL, 1mL Solution for Injection/Vial c) MK-1654 Sterile Saline Placebo (0.9% w/v Sodium Chloride), 0.7mL Dose Sterile Solution for Injection/Vial	a) Hospital Sibul b) Hospital Raja Perempuan Zainab II c) Sabah Women and Children's Hospital (Likas Hospital) d) Hospital Tunku Azizah (Hospital Wanita and Kanak-Kanak Kuala Lumpur) e) Hospital Pulau Pinang f) University of Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
9.	ANB019-301	Fasa III	a) Imsidolimab (ANB019) 100 mg/mL, 1mL per vial b) Placebo for Imsidolimab (ANB019) 100mg/mL vial, 1mL per vial	a) Universiti Kebangsaan Malaysia Medical Centre b) Hospital Kuala Lumpur c) Hospital Putrajaya d) Hospital Pakar Sultanah Fatimah e) Hospital Sultanah Aminah f) Hospital Raja Perempuan Zainab II	LULUS
10.	ANB019-302	Fasa III	a) Imsidolimab (ANB019) 100 mg/mL, 1mL per vial b) Placebo for Imsidolimab (ANB019) 100mg/mL vial, 1mL per vial	a) Universiti Kebangsaan Malaysia Medical Centre b) Hospital Kuala Lumpur c) Hospital Putrajaya d) Hospital Pakar Sultanah Fatimah e) Hospital Sultanah Aminah f) Hospital Raja Perempuan Zainab II	LULUS
11.	KBP5074-3-001	Fasa III	a) KBP-5074 Tablets 0.25 mg b) KBP-5074 Tablets 0.50 mg c) Matching Placebo for KBP-5074 0.25 mg or 0.5 mg Tablet	a) Hospital Raja Permaisuri Bainun b) Hospital Raja Perempuan Zainab II c) University Malaya Medical Centre d) Hospital Seri Manjung	LULUS
12.	MK-3655-001	Fasa III	a) MK-3655 33.3mg/mL, Solution for Injection, 1.5mL/vial b) MK-3655 100mg/mL, Solution for Injection, 1.5mL/vial c) MK-3655 Placebo, Solution for Injection, 1.5mL/vial	Hospital Kuala Lumpur	LULUS
13.	1378-0005	Fasa II	a) BI 690517 film-coated tablets 3 mg b) BI 690517 film-coated tablets 10 mg	a) Thomson Hospital Kota Damansara	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			c) Empagliflozin film-coated tablets 10mg d) Matching placebo to BI 690517 film-coated tablets 3 mg e) Matching placebo to BI 690517 film-coated tablets 10 mg f) Matching placebo to Empagliflozin film-coated tablets 10mg g) Synacthen® (Tetracosactide hexa-acetate) Solution for Injection 250 µg/ 1mL ampoule	b) Universiti Kebangsaan Malaysia Medical Centre (PPUKM) c) Hospital Raja Perempuan Zainab II	

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN FEBRUARI 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	BE.677/EQL/2021	Kajian BE	Apixaban Tablet 5mg	Clinical & Bioanalytical Site: PT Equilab International Jl. RS. Fatmawati Persil 33, Jakarta 12430 - Indonesia	LULUS
2.	ARL/21/262	Kajian BE	Linagliptin Film-Coated Tablets 5 mg	Clinical Site: Accutest Research Laboratories (I) Pvt. Ltd. 101 to 113 & 201 to 204, 1st and 2nd floor, Synergy Square Complex, Krishna Industrial Estate, BIDD, Gorwa, Vadodara – 390016, India Bioanalytical Site: Accutest Research Laboratories (I) Pvt. Ltd., A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai –400709, Maharashtra, India	LULUS
3.	AG348-C-017	Fasa III	a) AG-348 Sulfate Hydrate Tablets 100 mg b) Placebo to AG-348 Sulfate Hydrate Tablets	a) Hospital Tengku Ampuan Afzan b) Sarawak General Hospital c) Hospital Sultanah Bahiyah d) Hospital Sultanah Aminah e) Hospital Queen Elizabeth f) Hospital Tunku Azizah g) Hospital Pulau Pinang h) Hospital Ampang	LULUS
4.	AG348-C-018	Fasa III	a) AG-348 Sulfate Hydrate Tablets 100 mg b) Placebo to AG-348 Sulfate Hydrate Tablets	a) Hospital Tengku Ampuan Afzan b) Sarawak General Hospital c) Hospital Sultanah Bahiyah	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
				d) Hospital Sultanah Aminah e) Hospital Queen Elizabeth f) Hospital Tunku Azizah g) Hospital Pulau Pinang h) Hospital Ampang	
5.	849-010	Fasa III	a) MRTX849 tablets, 200mg b) Cetuximab 500 mg/100 mL (5 mg/mL), Solution for infusion, Vial c) Fluorouracil 1000 mg/20 mL (50 mg/mL), Solution for injection, Vial d) Fluorouracil 5000mg/100mL (50 mg/mL), Solution for injection, Vial e) Irinotecan Hydrochloride 500 mg/25 mL (20 mg/mL), Concentrate for solution for infusion, Vial f) Oxaliplatin 200mg/40mL (5 mg/mL), Concentrate for solution for infusion, Vial g) Calcium Folate, Solution for injection or infusion, 300 mg/30 mL, Vial	a) Beacon Hospital Sdn Bhd b) Institut Kanser Negara c) Hospital Kuala Lumpur d) Hospital Sultan Ismail e) University Malaya Medical Centre	LULUS
6.	AT-1501-N205	Fasa IIa	AT-1501, 190mg, Lyophilized powder	a) University Malaya Medical Centre b) Hospital Tengku Ampuan Afzan	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MAC 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	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

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Ahmedabad – 382481, Gujarat, India	
6.	BX-BE21-AMP-006	Kajian BE	Amipride Tablets 400mg	Clinical site: Clinical Research Ward (CRW) Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor Bioanalytical site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Pulau Pinang	LULUS
7.	226688	Fasa II/III	80mg (10mg/ml) of PRL3-zumab in 8.0 mL solution per vial	a) Hospital Kuala Lumpur b) Hospital Pulau Pinang	LULUS
8.	AT-02A-002	Fasa II	a) AT-752 250 mg tablet b) AT-752 250 mg placebo tablet	a) Hospital Seberang Jaya b) Hospital Sultanah Nur Zahirah	LULUS
9.	F901318/0041	Fasa III	a) 30mg Olorofim film-coated tablet b) 50mg AmBisome®, Liposomal Amphotericin B Powder for dispersion for infusion	a) Hospital Ampang b) University Malaya Medical Centre	LULUS
10.	CAIN457A02001B	Fasa IV	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	a) Hospital Umum Sarawak b) University Malaya Medical Centre	LULUS
11.	D967YC00001	Fasa Ib	a) DS-8201a Powder for concentrate for solution for infusion 100mg/vial	a) Hospital Umum Sarawak b) Institut Kanser Negara c) University Malaya Medical Centre d) Hospital Pulau Pinang	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	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

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN APRIL 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	C1B01830	Kajian BE	Pitolisant Tablets 17.8 mg	Clinical site: Clantha Research Limited Property No 2A, Block A, Sector 63, Gautambudh Nagar, Noida - 201301, Uttar Pradesh, India (Dr. Rishabh Jain) Bioanalytical site: Clantha Research Limited Clantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad-382210, Gujarat, India	LULUS
2.	C1B01831	Kajian BE	Pitolisant Tablets 17.8 mg	Clinical site: Clantha Research Limited Property No 2A, Block A, Sector 63, Gautambudh Nagar, Noida - 201301, Uttar Pradesh, India (Dr. Rishabh Jain) Bioanalytical site: Clantha Research Limited Clantha Corporate,	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad-382210, Gujarat, India	
3.	0456-21	Kajian BE	Pazopanib Tablets 200mg	Clinical & 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
4.	023-21	Kajian BE	Pregabalin Hovid 300mg Capsules	Clinical & Bioanalytical site: RA Chem Pharma Limited Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
5.	NS-018-201	Fasa IIb	NS-018 100mg (40 Tablets)	a) Hospital Ampang b) Hospital Raja Perempuan Zainab II c) Hospital Pulau Pinang d) Hospital Sultanah Aminah e) Hospital Queen Elizabeth f) Sunway Medical Centre g) Hospital Raja Permaisuri Bainun h) University Malaya Medical Centre	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0039-22	Kajian BE	Ezetimibe and Atorvastatin Tablets 10 mg/40 mg	Clinical 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 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
2.	ARL/21/247	Kajian BE	Sotalol Tablets 160 mg	Clinical site: Accutest Research Lab (I) Pvt. Ltd. 4th Floor, The Grand Monarch Near Seema Hall, Anand Nagar Road, Satellite, Ahmedabad-380015, India.	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Bioanalytical site: Accutest Research Laboratories (I) Pvt. Ltd., A-31/77, M.I.D.C, T.T.C Industrial Area, Khairane, Navi Mumbai – 400709, Maharashtra, India.	
3.	001-22	Kajian BE	Escitalopram Tablet 10mg	Clinical & Bioanalytical site: RA Chem Pharma Limited, Clinical Research & Biosciences Division, Plot-No. 26 & 27, Technocrat Industrial Estate (TIE), Balanagar, Hyderabad-500037, India	LULUS
4.	MECID No, UMMC: 202086-8956; NMRR, MOH: 60482; JEPeM, USM: USM/JEPeM/21070522	Fasa II	INJECSOL Vitamin C (Ascorbic Acid Injection 1g/5mL)	a) University of Malaya Medical Centre b) Hospital Universiti Sains Malaysia c) Hospital Kuala Lumpur (HKL)	LULUS
5.	VICSEP	Fasa II	a) INJECSOL Vitamin C (Ascorbic Acid Injection 1g/5mL) b) INFUSOL® D5 (Dextrose 5% w/v Intravenous Infusion BP)	a) Hospital Raja Permaisuri Bainun b) Hospital Sultanah Bahiyah c) Hospital Raja Perempuan Zainab II	LULUS
6.	VT3996-301	Fasa 1b/II	a) Viracta VRx-3996 (nanatinostat) tablets, 10 mg	a) Hospital Umum Sarawak	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			b) Valganciclovir 450 mg tablets (Valganciclovir Tablets, USP)	b) University Malaya Medical Centre c) Institut Kanser Negara	
7.	1443-0002	Fasa Ib	a) BI 765063 50mg/mL solution for infusion b) BI 754091 20mg/mL solution for infusion c) BI 836880 10mg/mL solution for infusion	a) University Malaya Medical Centre b) Hospital Umum Sarawak c) Institut Kanser Negara d) Hospital Sultan Ismail	LULUS
8.	CPI 0610-04	Fasa III	a) CPI-0610 25 mg film-coated tablet b) CPI-0610 100 mg film-coated tablet c) Placebo for CPI-0610 25 mg film-coated tablet d) Placebo for CPI-0610 100 mg film-coated tablet	a) Hospital Queen Elizabeth b) Hospital Pulau Pinang c) Sunway Medical Centre d) Hospital Sultanah Aminah e) Hospital Sultanah Bahiyah f) University Malaya Medical Centre g) Hospital Ampang	LULUS
9.	INS1009-202	Fasa IIb	a) Treprostinil Palmitil Inhalation Powder 80µg capsules b) Treprostinil Palmitil Inhalation Powder 160µg capsules c) Treprostinil Palmitil Inhalation Powder 320µg capsules d) Treprostinil Palmitil Inhalation Powder placebo capsules	a) Hospital Tengku Ampuan Afzan b) Hospital Serdang c) UiTM Medical Specialist Centre d) Hospital Sultanah Bahiyah	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUN 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	D9075C00001	Fasa III	10mL Durvalumab (MEDI4736) Concentrate for solution for infusion, 50mg/mL (500mg/vial)	a) Hospital Umum Sarawak b) University Malaya Medical Centre c) Hospital Sultan Ismail d) Beacon Hospital Sdn Bhd	LULUS
			5mL Domvanalimab (AB154) Concentrate for solution for infusion. 60 mg/mL (300 mg/vial)		
2.	CLOU064C12301	Fasa III	LOU064 (Remibrutinib) 100 mg Film-coated tablet	a) Hospital Kuala Lumpur b) Hospital Seberang Jaya c) Hospital Sultanah Nur Zahirah	LULUS
			Teriflunomide 14 mg hard gelatin capsule with tablet content (HGCT)		
			Placebo to LOU064 (Remibrutinib) 100mg Film-coated tablet		
			Placebo to Teriflunomide 14 mg hard gelatin capsule with tablet content (HGCT)		
3.	GT0918-US-3002	Fasa III	Proxalutamide (GT0918), 100 mg tablet	a) Hospital Sultanah Nur Zahirah b) Hospital Raja Perempuan Zainab II c) Hospital Tuanku Fauziah d) Hospital Tawau	LULUS
			Placebo for Proxalutamide (GT0918), 100 mg tablet		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUL 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BX-BE22-AMP-001	Kajian BE	Gapentin Capsule 300mg	<p>Clinical Site: Clinical Research Ward, Clinical Trial Unit, Hospital Ampang</p> <p>Bioanalytical Site: Bioxis Sdn Bhd PMT 1241, Jalan Perindustrian Bukit Minyak 8, Taman Perindustrian Bukit Minyak, 14100 Simpang Ampat, Penang</p>	LULUS
2.	0064-22	Kajian BE	Eltrombopag Tablets 75 mg	<p>Clinical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India</p> <p>Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India</p>	LULUS BERSYARAT
3.	0065-22	Kajian BE	Eltrombopag Tablets 75 mg	<p>Clinical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India</p>	LULUS BERSYARAT

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				Bioanalytical Site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India	
4.	CVAY736K12301	Fasa III	VAY736 (Ianalumab) 150mg/1ml Solution for Injection In Pre-filled Syringe VAY736 (Ianalumab) Placebo/1ml Solution for Injection In Pre-filled Syringe	a) Hospital Sultanah Nur Zahirah b) Hospital Sibul c) Hospital Kuala Lumpur	LULUS
5.	1346-0012	Fasa III	BI 425809 Film-Coated Tablets 10mg Matching placebo to BI 425809 Film-Coated Tablets 10mg	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Hospital Tuanku Jaáfar d) Hospital Sentosa Kuching e) Hospital Raja Permaisuri Bainun	LULUS
6.	MK-6482-022	Fasa III	Belzutifan (MK-6482) 40mg Tablet Belzutifan (MK-6482) 40mg Tablet Placebo MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial	a) Hospital Umum Sarawak b) Hospital Pulau Pinang c) University Malaya Medical Center	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
7.	ZWI-ZW25-301	Fasa III	ZW25 300mg Powder for concentrate for solution for infusion	a) Institut Kanser Negara b) Pantai Hospital Kuala Lumpur c) Hospital Pulau Pinang d) Hospital Umum Sarawak e) University Malaya Medical Center	LULUS
			BGB-A317 100mg/10mL Concentrate for solution for infusion		
			Trastuzumab Injection 440mg(20ml)		
8.	D910VC00001	Fasa III	25mL Tremelimumab Concentrate for Solution for Infusion. 20mg/mL (25mg/vial)	a) University Malaya Medical Center b) Institut Kanser Negara c) Pantai Hospital Kuala Lumpur d) Hospital Umum Sarawak e) Hospital Pulau Pinang	LULUS
			10mL Durvalumab (MEDI4736) concentrate for solution for infusion, 50mg/mL (500mg/vial)		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OGOS 2022

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	HIPRA-HH-7	Fasa IIb	COVID-19 Vaccine HIPRA (PHH-1V) Emulsion for Injection, 40µg/0.5 mL in 2 mL vial	a) Hospital Pulau Pinang	LULUS
2.	61186372NSC30 04	Fasa III	JNJ-61186372 co- formulated with rHuPH20, 1600mg (160mg/mL), 10mL Solution	a) University Malaya Medical Centre b) Beacon Hospital Sdn Bhd c) Sunway Medical Centre d) Hospital Umum Sarawak e) Pantai Hospital Kuala Lumpur	LULUS
			JNJ-61186372 co- formulated with rHuPH20, 2240mg (160mg/mL), 14mL Solution		
			JNJ-61186372 350mg (50/mL), 7mL Solution		
			Lazertinib 80mg tablet		
3.	D5671C00006	Fasa IIb/III	1 pre-filled multi-dose pen 2.7 mL Cotadutide (MEDI0382) Solution for injection 1 mg/mL	a) University Malaya Medical Centre b) Pusat Perubatan Universiti Kebangsaan Malaysia c) Hospital Universiti Sains Malaysia d) Subang Jaya Medical Centre e) Pantai Hospital Kuala Lumpur f) Hospital Tuanku Ja'afar	LULUS
			1 pre-filled multi-dose pen 2.7 mL Cotadutide (MEDI0382) Solution for injection 5 mg/mL		
			1 pre-filled multi-dose pen 2.7 mL Cotadutide		

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			(MEDI0382) Solution for injection 1 mg/mL matching Placebo 1 pre-filled multi-dose pen 2.7 mL Cotadutide (MEDI0382) Solution for injection 5 mg/mL matching Placebo		
4.	HREC/20/QCHQ/64068	Fasa III	Erdosteine 300mg Capsule Erdosteine Placebo 300mg Capsule	University Malaysia Medical Centre	LULUS
5.	R3918-PNH-2021	Fasa III	Pozelimab (REGN3918) 200 mg/mL solution, 2.0 mL, vial Cemdisiran (ALN-CC5) 200 mg/mL solution, 0.5 mL in a 2 mL vial Ravulizumab 100mg/mL, 3mL injection for intravenous use, 1 vial per carton	a) Hospital Ampang b) Hospital Tengku Ampuan Afzan c) Queen Elizabeth Hospital	LULUS
6.	MK-7684A-006	Fasa III	MK-7684A 10/10 mg/mL, Solution for Infusion, 20mL vial Durvalumab 50 mg/mL, Concentrate for Solution for Infusion, 2.4mL Vial	a) Hospital Pulau Pinang b) Hospital Kuala Lumpur c) University Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			Carboplatin 10mg/mL, Concentrate for Solution for Infusion, 60ml Vial		
			Paclitaxel 6mg/mL, Concentrate for Solution for Infusion, 16.7ml Vial		
			Etoposide 20 mg/mL, Concentrate for Solution for Infusion, 5ml Vial		
			Cisplatin 1 mg/mL, 50 mL Concentrate for Solution for Infusion		
			Pemetrexed, Lysophilized Powder for Solution for Infusion, 500mg/Vial		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0182-22	Kajian BE	Imatinib Tablets 400 mg	Clinical and 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
2.	CBCC/2022/003	Kajian BE	Capecitabine Tablets USP, 500mg	Clinical Site: a) KLES Dr. Prabhakar Kore Hospital and Medical Research Centre Belgaum Nehru Nagar, Belagavi, Karnataka-590010, India b) Sanjeevani CBCC USA Cancer Centre, In front of Jain Mandir, Dawada Colony, Pachpedi Naka, Raipur, Chhattisgarh -492001, India c) CIMET's Inamdar Multispeciality Hospital Building S. No. 15, Behind KPCT Mall, Fatima Nagar, Pune-411040, Maharashtra, India d) HCG Manavata Cancer Centre Behind Shivang Auto, Mumbai Naka, Nashik-422002, Maharashtra, India	LULUS

				<p>e) Erode Cancer Centre, SSH 1/393, Velavan Nagar, Perundurai Road, Thindal, Erode-638012, Tamil Nadu, India</p> <p>f) Kiran Multi Super Specialty Hospital Near Sumul Dairy, Katargam, Surat, Gujarat 395004, India</p> <p>g) Sunshine Global Hospital Dumas Road, Beside Big Bazar, Piplod, Surat, Gujarat 395007, India</p> <p>h) Thanjavur Cancer Centre 165/16, By- pass Road, Madhakkottai, Thulukkampatti, Thanjavur-613005, Tamilnadu, India</p> <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>	
3.	CBR-BD-22-003	Fasa IV	Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 150 million cells in 15 ml of Cryobag)	Hospital Canselor Tuanku Muhriz	LULUS

			Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 200 million cells in 15 ml of Cryobag)		
4.	CBR-PAD-22-004	Fasa IV	Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 150 million cells in 15 ml of Cryobag)	Hospital Canselor Tuanku Muhriz	LULUS
			Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 200 million cells in 15 ml of Cryobag)		
5.	ARL/22/137	Kajian BE	Erlotinib Tablets 150 mg	Clinical site: Accutest Research Laboratories (I) Pvt. Ltd., 101 to 113 & 201 to 204, 1st and 2nd Floor, Synergy Square Complex, Krishna Industrial Estate, B.I.D.C., Gorwa, Vadodara – 390016, Gujarat, India.	LULUS
			Erlotinib Tablets 150 mg		

6.	CJDQ443B12301	Fasa III	JDQ443 100mg Tablet	<ul style="list-style-type: none"> a) Beacon Hospital b) Sarawak General Hospital c) Sunway Medical Centre d) Pantai Hospital Kuala Lumpur e) University Malaya Medical Centre 	LULUS
7.	MR43808	Fasa III/IV	Faricimab 6mg/0.05mL Vial	<ul style="list-style-type: none"> a) Hospital Shah Alam b) Hospital Selayang 	LULUS
8.	NN8640-4467	Fasa III	Somapacitan 5 mg/1.5 mL Solution for Injection	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Universiti Sains Malaysia (HUSM) c) Hospital UiTM 	LULUS
			Somapacitan 10 mg/1.5 mL; Solution for Injection		
			Somapacitan 15 mg/1.5 mL; Solution for Injection		
			Norditropin® 10 mg/1.5 mL; Solution for Injection		
9.	CNTO1959CRD3 004	Fasa III	Guselkumab 100 mg/1 ml Solution for Infusion or Injection	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Tengku Ampuan Afzan c) Hospital Raja Permaisuri Bainun d) Hospital Sultanah Aminah e) Hospital Universiti Sains Malaysia 	LULUS

			Guselkumab 200 mg/2 ml in Prefilled Syringe with YpsoMate Autoinjector (PFS-Y)		
			Placebo for Guselkumab 100 mg/1 ml Solution		
			Placebo for Guselkumab 200 mg/2 ml in Prefilled Syringe with YpsoMate Autoinjector (PFS-Y)		
10.	1366-0031	Fasa II	BI 685509 1mg Film-coated Tablet	a) University Malaya Medical Centre b) Hospital Selayang	LULUS
			BI 685509 2mg Film-coated Tablet		
			BI 685509 3mg Film-coated Tablet		
			BI 685509 Matching Placebo for 1mg Film-coated Tablet		
			BI 685509 Matching Placebo for 2mg Film-coated Tablet		
			BI 685509 Matching Placebo for 3mg Film-coated Tablet		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OKTOBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	032-22	Kajian BE	Aprepitant Capsule 125mg	Clinical site & Bioanalytical site: Ecron Acunova Limited (Formerly known as Manipal Acunova) IV floor, Sri Shirdi Sai Baba Cancer Hospital & Research Centre, Manipal- 576 104, India.	LULUS
2.	0366-21	Kajian BE	Telmisartan Tablets 80 mg	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, India	LULUS
3.	417-201-00007	Fasa III	Sibeprenlimab (VIS649) 200mg/mL solution for injection in 2mL vial Placebo for VIS649 200mg/mL solution for injection	i. Hospital Canselor Tuanku Muhriz UKM ii. University of Malaya Medical Centre iii. Hospital Tengku Ampuan Afzan iv. Hospital Tuanku Ja'afar Seremban v. Hospital Kuala Lumpur vi. Hospital Raja Permaisuri Bainun	LULUS
4.	417-201-00012	Fasa III/IV	Sibeprenlimab (VIS649) 200mg/mL solution for injection in 2mL vial	i. Hospital Canselor Tuanku Muhriz UKM ii. University of Malaya Medical Centre iii. Hospital Tengku Ampuan Afzan	LULUS
5.	NN9838-4609	Fasa III	CagriSema 1.0mg/mL + 0.5mg/mL, Solution for Injection CagriSema 2.0mg/mL + 1.0mg/mL, Solution for Injection	a) Universiti Teknologi Mara b) Hospital Universiti Sains Malaysia c) Hospital Umum Sarawak d) Hospital Melaka	LULUS

			CagriSema 4.0mg/mL + 2.0mg/mL, Solution for Injection	e) Hospital Miri f) Hospital Tuanku Jaafar g) Hospital Putrajaya h) Hospital Canselor Tuanku Muhriz i) Hospital Seri Manjung		
			CagriSema 6.8mg/mL + 3.4mg/mL, Solution for Injection			
			CagriSema 9.6mg/mL + 4.8mg/mL, Solution for Injection			
			Placebo Cagrilintide B and Placebo Semaglutide I			
6.	DZ2019E0001	Fasa I/II	DZD9008 150mg Tablet	a) Hospital Kuala Lumpur b) Hospital Sultan Ismail c) Pusat Perubatan Universiti Malaya	LULUS	
			DZD9008 200mg Tablet			
7.	64281802DNG20 04	Fasa II	JNJ-64281802 200mg Oral Film-coated Tablet	a) Klinik Kesihatan Kuang b) Hospital Taiping c) University Malaya Medical Centre	LULUS	
			JNJ-64281802 50mg Oral Film- coated Tablet			
			Matching Placebo for 200mg JNJ-64281802 Oral Film-coated Tablet			
			Matching Placebo for 50mg JNJ-64281802 Oral Film-coated Tablet			
8.	20210096	Fasa III	Bemarituzumab (AMG 552), 20mg/mL Solution For Injection, 20mL Filled Vial	a) University Malaya Medical Centre b) Hospital Umum Sarawak c) Hospital Kuala Lumpur	LULUS	
			Bemarituzumab (AMG 552), 20mg/mL Matching Placebo Solution For Injection, 20mL Filled Vial			

9.	TCH-306	Fasa III	Lonapegsomatropin 12.1 mg hGH / vial, Powder for Injection	a) Hospital Umum Sarawak	LULUS
			Placebo for Lonapegsomatropin 12.1 mg hGH / vial, Powder for Injection	b) Hospital Putrajaya	
			Norditropin® 5 mg/ 1.5 mL Solution for Injection in Pre-Filled Pen	c) University Malaya Medical Centre	
			Pre-filled Syringe with 1.0 mL of Sterile Water for Injection for Reconstitution of Lonapegsomatropin or Placebo	d) Hospital Universiti Sains Malaysia	
				e) Hospital Pulau Pinang	
				f) Hospital Melaka	

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN NOVEMBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	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

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN DISEMBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	236-22	Kajian BE	Mycophenolate Mofetil tablets 500 mg	Clinical site & Bioanalytical site: Axis Clinical Limited 1-121/1, Survey No. 66 & 67 (Part), Miyapur, Serilingampally, Hyderabad, Telangana, 500049, India	LULUS
2.	BE22-003	Kajian BE	Azimac Tablet 500mg	Clinical site & Bioanalytical site: Questra Bio-Clinical Research Centre, Questra Clinical Research Sdn. Bhd. No. 6, Jalan Desa Pauh, Taman Desa Pauh, 13700 Permatang Pauh, Pulau Pinang.	LULUS
			Zithromax Tablet 500mg		
3.	DNDi-OXA-07- HAT	Fasa I	Acoziborole 320mg, Tablet	Clinical Trial Unit, Hospital Ampang	LULUS
			BECHILAR 3 mg/mL Syrup		
			Midazolam-ratiopharm® 2 mg/mL Oral Solution		
4.	MBI-003-LIVE	Fasa II	AlloStim® cryopreserved 1.0x10 ⁷ cells/ml, 0.5ml in 2.0ml cryovial	a) Aurelius Hospital Nilai b) Hospital Sultan Ismail c) Hospital Sultanah Bahiyah d) Hospital Pulau Pinang	LULUS

5.	UPAMOSTAT-LHG/002	Fasa II	Upamostat 200mg capsule	Hospital Ampang	LULUS
			Placebo to Upamostat 200mg capsule		
6.	C1B02537	Kajian BE	Pitolisant Tablets 17.8 mg	<p>Clinical site: Cliantha Research Limited Property No 2A, Block A, Sector 63, Gautambudh Nagar, Noida - 201301, Uttar Pradesh, India</p> <p>Bioanalytical site: Cliantha Research Limited Cliantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad-382210, Gujarat, India</p>	LULUS
7.	C1B02538	Kajian BE	Pitolisant Tablets 17.8 mg	<p>Clinical site: Cliantha Research Limited Property No 2A, Block A, Sector 63, Gautambudh Nagar, Noida - 201301, Uttar Pradesh, India</p> <p>Bioanalytical site: Cliantha Research Limited Cliantha Corporate,</p>	LULUS

				TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad-382210, Gujarat, India	
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