

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Nama Pemohon	Pusat Kajian Klinikal	Status Permohonan
1	0200-22	Kajian BE	Linagliptin 5mg Film-coated Tablets	Xepa-Soul Pattinson (Malaysia) Sdn. Bhd.	Tapak Klinikal & Bionalitikal: Lambda Therapeutic Research Ltd. Lambda house, Plot No.38, Survey no. 388, Near Silver Oak Club, S.G. Highway, Gata, Ahmedabad-382481, Gujarat, India.	LULUS
2	PT3_AFLD	Fasa II	1) Tocovid TM Suprabio TM 200mg Capsule 2) Placebo to Match Tocovid Suprabio Capsule	Hovid Berhad	Hospital Canselor Tuanku Muhriz UKM	LULUS
3	D361DC00001	Fasa Ib/III	1) Capivasertib (AZD5363) 200mg Tablet 2) Capivasertib (AZD5363) 160mg Tablet 3) 5 mL Fulvestrant Solution for injection 50 mg/mL 4) Tablet Palbociclib 75mg 5) Tablet Palbociclib 100mg 6) Tablet Palbociclib 125mg 7) Capsule Palbociclib 75mg 8) Capsule Palbociclib 100mg 9) Capsule Palbociclib 125mg 10) Ribociclib Tablet 200mg	AstraZeneca Sdn Bhd	a) Pantai Hospital Kuala Lumpur b) Hospital Pulau Pinang c) University Malaya Medical Centre d) Sarawak General Hospital e) Penang Adventist Hospital f) Beacon Hospital g) Institut Kanser Negara h) Hospital Kuala Lumpur	LULUS
4	EFC16035	Fasa III	1) Tolebrutinib/SAR442168 60 mg film coated tablet 2) Placebo matching with tolebrutinib (SAR442168)/ Film Coated Tablet	Sanofi-Aventis (Malaysia) Sdn Bhd	Hospital Kuala Lumpur	LULUS
5	D926QC00001	Fasa III	1) DS-1062a Lyophilised powder for concentrate for solution for infusion, 100 mg/vial 2) 10 mL Durvalumab (MED14736) Concentrate for solution for infusion, 50 mg/mL (500 mg/vial)	AstraZeneca Sdn Bhd	a) Hospital Pulau Pinang b) University Malaya Medical Centre c) Pantai Hospital Kuala Lumpur d) Hospital Umum Sarawak e) Institut Kanser Negara	LULUS
6	WA43966	Fasa III	1) RO7434656 70 mg/0.7 ml, solution for injection in a vial 2) Matching placebo for RO7434656 70 mg/0.7 ml, solution for injection in a vial	PPD Development (S) Pte. Ltd	a) Hospital Tengku Ampuan Afzan b) Hospital Sibul c) Hospital Ampang d) Hospital Miri e) Hospital Seri Manjung f) Hospital Taiping g) Universiti Malaya Medical Centre h) Hospital Kuala Lumpur	LULUS

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7	FPSMA-01	Fasa III	F-18 PSMA-1007 90-110 mCi/ml Injectable Solution	Jabatan Perubatan Nuklear, Institut Kanser Negara	Fasiliti PET-CT, Jabatan Perubatan Nuklear, Institut Kanser Negara	LULUS
8	ITOP-322-016	Fasa III	1) Itopride Hydrochloride 150mg Extended Release Tablets 2) GANATON® 50mg Tablets (Itopride Hydrochloride)	Antah Pharma Sdn Bhd	a) University Malaya Medical Centre (UMMC) b) Hospital Queen Elizabeth c) Hospital Sultanah Bahiyah d) Pantai Hospital Kuala Lumpur	LULUS
9	FF-2021-519	Fasa IV	1) Bio-D3 800IU Capsule 2) Matching Placebo for Bio-D3 800 IU Capsule	Pharma Nord Sdn Bhd	Hospital Pakar Kanak-kanak UKM	LULUS
10	LG-GDCL010	Fasa III	1) Tigulixostat 100mg Tablet 2) Tigulixostat 200mg Tablet 3) Allopurinol 100mg Over-encapsulated Tablet (Capsule) 4) Allopurinol 200mg Over-encapsulated Tablet (Capsule) 5) Allopurinol 300mg Over-encapsulated Tablet (Capsule) 6) Matching Placebo to Tigulixostat 100mg Tablet 7) Matching Placebo to Tigulixostat 200mg Tablet 8) Matching Placebo to Allopurinol 100mg/200mg/300mg Over-encapsulated Tablet (Capsule)	Parexel International (Malaysia) Sdn. Bhd.	a) Hospital Selayang b) Sarawak General Hospital c) Hospital Seri Manjung d) Klinik Kesihatan Masjid Tanah e) Klinik Kesihatan Kuala Lumpur f) Klinik Kesihatan Kuang g) University Malaya Medical Centre	LULUS
11	R3767-ONC-2235	Fasa II/III	1) 16mL of 50mg/mL of Fianlimab (REGN3767) Liquid Solution in Vial 2) 7mL of 50mg/mL of Cemiplimab (REGN2810) Liquid Solution in Vial	Antah Pharma Sdn. Bhd.	a) Hospital Sultan Ismail b) Hospital Pulau Pinang c) Mahkota Medical Centre d) Hospital Tengku Ampuan Afzan e) Institut Kanser Negara f) Hospital Kuala Lumpur	LULUS

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12	R3767-ONC-2236	Fasa II/III	1) 16mL of 50mg/mL of Fianlimab (REGN3767) Liquid Solution in Vial 2) 7mL of 50mg/mL of Cemiplimab (REGN2810) Liquid Solution in Vial 3) 50mL of Paclitaxel AqVida 6 mg/mL Concentrate for Solution for Infusion 4) Carboplatin Hikma 10 mg/mL Solution for Infusion, 150mg 5) 20mL of Pemetrexed EVER Pharma 25 mg/mL Concentrate for Solution for Infusion 6) Cisplatin Concentrate for Solution for Infusion 1mg/mL 100mL	Antah Pharma Sdn. Bhd.	a) Hospital Sultan Ismail b) Hospital Pulau Pinang c) Mahkota Medical Centre d) Mount Miriam Cancer Hospital e) Hospital Tengku Ampuan Afzan f) Institut Kanser Negara g) Hospital Umum Sarawak	LULUS
13	SB27-3004	Fasa III	1) Pembrolizumab (SB27) 100 mg/4 ml (25 mg/ml) concentrate for solution for infusion 2) Pembrolizumab (Keytruda®) 100 mg/4 ml (25 mg/ml) concentrate for solution for infusion 3) Carboplatin (10 mg/ml) concentrate for solution for infusion 4) Pemetrexed (25 mg/ml) concentrate for solution for infusion	Antah Pharma Sdn. Bhd.	a) Hospital Pulau Pinang b) Hospital Tengku Ampuan Afzan c) University Malaya Medical Center (UMMC) d) National Cancer Centre	LULUS
14	P-SP420-THAL-01	Fasa II	SP-420 Capsules 400mg	Questra Clinical Research Sdn. Bhd.	a) Hospital Sultanah Aminah b) Tuanku Ja'afar Hospital Seremban c) Hospital Raja Perempuan Zainab II d) Hospital Sultanah Bahiyah e) Hospital Tengku Ampuan Afzan f) Hospital Ampang	LULUS
15	VT3996-202	Fasa II	1) VRx-3996 (nanatinostat) tablets, 10 mg 2) Valganciclovir 450 mg Tablets	Questra Clinical Research Sdn. Bhd.	a) Hospital Umum Sarawak b) University Malaya Medical Centre	LULUS
16	747-308	Fasa II/III	1) OCA, 0.1 mg tablet 2) OCA, 1.5 mg tablet 3) Matching Placebo for OCA, 0.1 mg tablet 4) Matching Placebo for OCA, 1.5 mg tablet	Syneos Health Malaysia Sdn. Bhd.	a) Universiti Malaya Medical Centre b) Hospital Raja Perempuan Zainab II	LULUS
17	D9723C00001	Fasa III	1) Tablet AZD5305 20mg 2) Placebo for Tablet AZD5305 20mg	AstraZeneca Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Hospital Sultan Ismail d) Hospital Umum Sarawak e) Hospital Likas f) Hospital Kuala Lumpur	LULUS

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18	PR/BE/23/324	Kajian BE	Noriquine 200mg Tablet	Noripharma Sdn. Bhd.	Tapak Klinikal: Raptim Research Pvt. Ltd. A-226 (Clinical Unit), T.T.C Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India (Dr Raviraj Jagdhani) Tapak Bionalitikal: Raptim Research Pvt. Ltd. A-242, T.T.C Industrial Area, Mahape M. I.D.C., Navi Mumbai – 400710, India	LULUS
19	MK-2870-005	Fasa III	MK-2870 200mg/vial, Lyophilized powder for IV Infusion (MK-2870-005)	Merck Sharp & Dohme (Malaysia) Sdn. Bhd.	a) University Malaya Medical Centre b) Pantai Hospital Kuala Lumpur	LULUS
20	ARL-23-017	Kajian BE	1) Sitagliptin 100 mg Film-Coated Tablets 2) Januvia 100 mg Film-Coated Tablet	Hovid Berhad	Tapak Klinikal dan Tapak Bioanalitikal: Accutest Research Laboratories (I) Pvt. Ltd. A-31, M.I.D.C., T.T.C. Industrial Area, Khairne, Navi Mumbai, 400709 Maharashtra, INDIA.	LULUS
21	1807361301 (Previously known as 2015H0112)	Fasa II	1) Mixed Tocotrienols 200mg capsule 2) Mixed Tocotrienols 200mg Matching placebo capsule	Hovid Berhad	Indiana University Health University Hospital	LULUS
22	D9350C00001	First-In Human	1) AZD9592 100 mg/vial Powder for solution for infusion 2) IV Bag Protectant 1 mL/vial Concentrate for solution for infusion 3) Tablet Osimertinib 40mg 4) Tablet Osimertinib 80mg	AstraZeneca Sdn. Bhd.	Hospital Umum Sarawak	LULUS
23	D9800C00001	Fasa II	AZD0901 50mg / vial, Lyophilisate for concentrate for solution for infusion	AstraZeneca Sdn. Bhd.	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Sarawak General Hospital d) Institut Kanser Negara e) Hospital Sultan Ismail	LULUS

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24	AP063-003	Fasa III	1) AP063, 150 mg powder for concentrate for solution for infusion 2) Herceptin®, 150 mg powder for concentrate for solution for infusion 3) Docetaxel, 160mg/8mL concentrate for solution for infusion 4) Epirubicin Hydrochloride 200mg/100mL concentrate for solution for infusion 5) Cyclophosphamide, 500mg powder for solution for injection 6) Cyclophosphamide, 1000mg powder for solution for injection	Syneos Health Malaysia Sdn. Bhd.	a)University Malaya Medical Centre b)Columbia Asia Hospital – Bukit Rimau c)Institut Kanser Negara d)Hospital Pulau Pinang e)Sarawak General Hospital f)Hospital Sultan Ismail g)Hospital Al-Sultan Abdullah h)Hospital Kuala Lumpur	LULUS
25	MK-2870-004	Fasa III	1) MK-2870 200mg/vial, Lyophilized powder for IV Infusion 2) Docetaxel 20mg/mL, Solution for IV Infusion, 80mg vial 3) Pemetrexed, Lyophilized Powder for Solution for Infusion, 500mg/vial	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Hospital Umum Sarawak b) Hospital Raja Perempuan Zainab II c) Institut Kanser Negara	LULUS
26	MK-6194-006	Fasa II	1) MK-6194 3mg/mL, 1mL Sterile Solution for Injection / Pre-filled syringe 2) MK-6194 Placebo, 1mL Sterile Solution for Injection / Pre-filled syringe	Merck Sharp & Dohme (Malaysia) Sdn Bhd	a) Hospital Taiping b) University Malaya Medical Centre c) Hospital Tengku Ampuan Afzan d) Hospital Canselor Tuanku Muhriz UKM	LULUS
27	D5985C00002	Fasa III	1) MDI – Metered-dose Inhaler Pressurized Inhalation Suspension Budesonide/Glycopyrronium/Formoterol Fumarate (BGF HFO) 160/7.2/4.8 µg Per Actuation 2) MDI - Metered-dose Inhaler Pressurized Inhalation Suspension BGF Placebo 120 Actuations 3) MDI - Metered-dose Inhaler Pressurized Inhalation Suspension Budesonide/Glycopyrronium/Formoterol Fumarate (BGF) 160/7.2/4.8 µg Per Actuation	AstraZeneca Sdn. Bhd.	a) Hospital Pulau Pinang b) Institute of Respiratory Medicine c) Hospital Raja Permaisuri Bainun d) Hospital Sultanah Nur Zahirah	LULUS

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28	D4325C00010	Fasa III	1) Zibotentan/Dapagliflozin 0.25mg/10mg 2) Zibotentan/Dapagliflozin 0.75mg/10mg 3) Tablet Dapagliflozin 10mg	AstraZeneca Sdn Bhd	a) University Malaya Medical Centre b) Hospital Raja Permaisuri Bainun c) Hospital Seri Manjung	LULUS
29	22-002	Fasa IV	Zavicefta 2 g/0.5 g powder for concentrate for solution for infusion	University Malaya Medical Centre	University Malaya Medical Centre	LULUS