

STATUS KELULUSAN PERMOHONAN CTIL & CTX 2024

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Nama Pemohon	Pusat Kajian Klinikal	Jangkaan Tempoh Masa 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.	Tidak berkenaan	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	01-Jan-2023 hingga 10-Nov-2024	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	01-Jan-2024 hingga 02-Apr-2029	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	11-Feb-2023 hingga 02-Apr-2029	LULUS
5	D926QC00001	Fasa III	1) DS-1062a Lyophilised powder for concentrate for solution for infusion, 100 mg/vial 2) 10 mL Durvalumab (MEDI4736) 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	01-Feb-2024 hingga 01-Feb-2031	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 Sibu c) Hospital Ampang d) Hospital Miri e) Hospital Seri Manjung f) Hospital Taiping g) Universiti Malaya Medical Centre h) Hospital Kuala Lumpur	15-Nov-2023 hingga 31-Dic-2026	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	01-Jun-2022 hingga 01-Dis-2023	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	01-Jan-2024 hingga 30-May-2025	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	01-April-2022 hingga 31-Okt-2023	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	02-Jan-2024 hingga 31-Dis-2025	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	01-Jan-2024 hingga 11-Mac-2029	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	01-Jan-2024 hingga 31-Dis-2029	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	26-Jan-2024 hingga 01-Jul-2027	LULUS
14	P-SP420-THAL-01	Fasa II	SP-420 Capsules 400mg	Questa 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	27-Mei-2024 hingga 13-Okt-2025	LULUS
15	VT3996-202	Fasa II	1) VRx-3996 (nanatinostat) tablets, 10 mg 2) Valganciclovir 450 mg Tablets	Questa Clinical Research Sdn. Bhd.	a) Hospital Umum Sarawak b) University Malaya Medical Centre	22-Apr-2024 hingga 01-Feb-2027	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	31 -May-2024 hingga 31-May-2028	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	01-Mar-2024 hingga 31-Oct-2031	LULUS

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18	PR/BE/23/324	Kajian BE	Noriquine 200mg Tablet	Noripharma Sdn. Bhd.	<p>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)</p> <p>Tapak Bionalitikal: Raptim Research Pvt. Ltd. A-242, T.T.C Industrial Area, Mahape M.I.D.C., Navi Mumbai – 400710, India</p>	Tidak berkenaan	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.	<p>a) University Malaya Medical Centre</p> <p>b) Pantai Hospital Kuala Lumpur</p>	01-Feb-2024 hingga 29-Nov-2028	LULUS

*Data adalah diperolehi daripada laman sesawang National Medical Research Register (NMRR). Sila layari <https://nmrr.gov.my/research-directory> untuk maklumat terkini dan lanjut.