

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JANUARI 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	C1B02419	Kajian BE	Trametinib Tablets 2mg	Clinical Site & Bioanalytical Site: Clantha Research Limited Clantha Corporate, TP 86, FP 28/1, Off S.P. Ring Road, Sarkhej, Ahmedabad- 382210, Gujarat, India	LULUS
2.	HZNP-DAX-203	Fasa II	Daxdilimab 100mg/mL Solution (1mL/vial)	a) University Malaya Medical Centre b) Hospital Serdang	LULUS
3.	CAIN457I2401	Fasa IV	Secukinumab (AIN457) 150 mg/1 mL Solution for Injection in Pre Filled Syringe	a) Sarawak General Hospital b) Hospital Selayang c) University Malaya Medical Centre	LULUS
			Placebo for Secukinumab (AIN457) 150 mg/1 mL Solution for Injection in Pre Filled Syringe		
4.	ARV-1801-001	Fasa II	ARV-1801 300 mg Tablet	a) Hospital Sultanah Bahiyah b) Hospital Pulau Pinang c) Hospital Umum Sarawak	LULUS
			Placebo for ARV-1801 300mg Tablet		
5.	NN7769-4514	Fasa III	NNC0365-3769 B 5.0mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge	a) Hospital Ampang b) Hospital Queen Elizabeth I	LULUS
			NNC0365-3769 B 11.3mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge		
			NNC0365-3769 B 25.0mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge		
			NNC0365-3769 B 57.5mg/mL; Solution for Injection; 1 x 0.8 mL Cartridge		
6.	D9185C00001	Fasa III	Tozorakimab (MEDI3506) 150 mg/mL Solution for Injection	a) Hospital Miri	LULUS
			Placebo for Tozorakimab (MEDI3506) 150 mg/mL Solution for Injection		

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

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MAC 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	117-22	Kajian BE	Dabigatran Etexilate Capsules 150 mg	Clinical Site & Bioanalytical Site: VerGo Pharma Research Pvt. Ltd.	LULUS
2.	118-22	Kajian BE	Dabigatran Etexilate Capsules 150 mg	Clinical Site & Bioanalytical Site: VerGo Pharma Research Pvt. Ltd.	LULUS
3.	POD0031/CP/R	Phase II/III	Neuroncell-EX (Allogeneic Mesenchymal Stem Cells), 30 million cells in 1.8mL of cryoprotectants (90% human serum albumin and 10% dimethyl sulfoxide (DMSO)) in a 2.0mL polyethylene (PE) cryovial Placebo (1.8mL sterile normal saline in 2mL cryovial)	Hospital Canselor Tuanku Muhriz UKM	LULUS
4.	78934804CRD2001	Phase IIb	Guselkumab/Golimumab (JNJ-78934804) (100 mg/100 mg) in Pre-filled Syringe with UltraSafe Plus™ Passive Needle Guard (PFS-U) Golimumab 100 mg/1 ml in Pre-filled Syringe with UltraSafe Passive® Delivery System Placebo for Guselkumab 200 mg/2 ml in Pre-filled Syringe with Ultrasafe Plus™ Passive Needle Guard (PFS-U) Placebo for Guselkumab 20 ml Solution in Vial Guselkumab 100 mg/1 ml Solution for Infusion or Injection in Pre-filled Syringe	a) Hospital Pulau Pinang b) Hospital Sultanah Bahiyah c) Hospital Ampang d) Pusat Perubatan Universiti Malaya	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Placebo for Guselkumab 100 mg/1 ml Solution		
5.	VT-001-0070	Phase III	Atacicept 150 mg/mL pre-filled syringes Placebo for Atacicept 150 mg/mL pre-filled syringes Mycophenolate Mofetil 500 mg film-coated Tablet	Hospital Kuala Lumpur	LULUS
6.	JEP-2022-536	Phase IV	Mucosolvan® Injection Solution 15mg/2mL	Hospital Canselor Tuanku Muhriz UKM (HCTM)	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN APRIL 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	PR/BE/23/011	Kajian BE	Leflunomide Tablets, 20 mg	Clinical site & Bioanalytical site: Raptim Research Pvt. Ltd.	LULUS
2.	BX-BE22-AMP-002	Kajian BE	Barica Capsule 150mg	Clinical site: Clinical Research Ward, Hospital Ampang Bioanalytical site: Bioxis Sdn. Bhd.	LULUS
3.	0409-22	Kajian BE	Apixaban 5mg Tablet	Clinical site & Bioanalytical site: Lambda Therapeutic Research Ltd.	LULUS
4.	22-VIN-0523	Kajian BE	Pregabalin Hovid 50mg Capsule	Clinical site & Bioanalytical site: Veeda Clinical Research Ltd.	LULUS
5.	EDP 938-104	Fasa IIb	a) EDP-938 200mg Tablets b) EDP-938 200mg Placebo Tablets	a) Sultan Ahmad Shah Medical Centre @IIUM b) Hospital Miri	LULUS
6.	GS-US-576-6220	Fasa II	a) Sacituzumab govitecan, 200 mg Lyophilized powder for solution for infusion b) Pembrolizumab 4mL (25mg/mL) Concentrate for Solution for Infusion c) Cisplatin 0.5mg/mL (100mL) concentrate for solution for infusion d) Carboplatin 45 mL (10mg/mL) concentrate for solution for infusion	a) Hospital Tengku Ampuan Afzan b) Hospital Sultan Ismail c) Hospital Raja Permaisuri Zainab II d) University Malaya Medical Centre e) Hospital Kuala Lumpur f) Hospital Umum Sarawak g) Insitut Kanser Negara	LULUS
7.	20210144	Fasa III	a) AMG 451, 150mg/mL Solution for Injection, 2mL labelled volume b) Matching Placebo for AMG 451 Solution for Injection, 2mL labelled volume	a) Hospital Pulau Pinang b) Hospital Kuala Lumpur c) Hospital Queen Elizabeth d) Hospital Raja Permaisuri Bainun e) Hospital Sultan Ismail f) University Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
8.	MK-1026-008	Fasa III	<ul style="list-style-type: none"> a) MK-1026 (Nemtabrutinib) 5mg Film-Coated Tablets b) MK-1026 (Nemtabrutinib) 20mg Film-Coated Tablets c) Fludarabine 25mg/mL, Concentrate for Solution for Infusion, 2mL Vial d) Cyclophosphamide 1000mg Vial Powder for Solution for Injection e) Bendamustine 2.5mg/mL, Powder for Concentrate for Solution for Infusion, 40mL Vial f) Rituximab 10mg/mL, Concentrate for Solution for Infusion, 50mL Vial 	<ul style="list-style-type: none"> a) Hospital Ampang b) Hospital Sultanah Aminah 	LULUS
9.	D4191C00137	Fasa III	10 ML Durvalumab (MEDI4736) Concentrate For Solution For Infusion 50 mg/ml (500 mg/vial)	Sarawak General Hospital	LULUS
10.	STAR-221	Fasa III	<ul style="list-style-type: none"> a) Domvanalimab (AB154) for Injection, Concentrate for Solution for IV infusion, 60mg/ml in 5ml (300mg/vial) b) Zimberelimab (AB122) for Injection, Concentrate for Solution for IV Infusion, 30mg/ml in 4ml (120mg/vial) c) Nivolumab, Concentrate for solution for IV infusion (Sterile Concentrate), 100 mg/ 10ml Vial d) Nivolumab, Concentrate for Solution for IV infusion (Sterile Concentrate), 240mg/24 ml Vial e) Fluorouracil, Solution for Infusion/Injection, 500mg/10ml Vial f) Fluorouracil, Solution for infusion/injection, 1000mg/20ml Vial g) Fluorouracil, Solution for infusion/injection, 5000mg/100ml Vial 	<ul style="list-style-type: none"> a) Hospital Kuala Lumpur b) Hospital Pulau Pinang c) Hospital Umum Sarawak d) University Malaya Medical Centre 	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			<ul style="list-style-type: none"> h) Leucovorin, Solution for Injection, 1000mg/100ml Vial i) Oxaliplatin, Concentrate for solution for IV infusion, 100mg/20ml Vial j) Oxaliplatin, Concentrate for solution for IV infusion, 200 mg/40ml Vial k) Capecitabine, Film-Coated Tablets, 150mg l) Capecitabine, Film-Coated Tablets, 500mg 		
11.	D7830C00004	Fasa IIb	<ul style="list-style-type: none"> a) AZD2693 25mg/mL solution for injection, containing 1.2mL solution/vial b) AZD2693 80mg/mL solution for injection, containing 1.2mL solution/vial c) Placebo for AZD2693 25mg/mL or 80mg/mL solution for injection, containing 1.2mL solution/vial d) AZD2693 25mg/mL solution for injection, containing 1.3mL solution/vial e) AZD2693 80mg/mL solution for injection, containing 1.3mL solution/vial f) Placebo for AZD2693 25mg/mL or 80mg/mL solution for injection, containing 1.3mL solution/vial 	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Pulau Pinang 	LULUS
12.	1368-0098	Fasa IIb/III	<ul style="list-style-type: none"> a) BI 655130 (Spesolimab), Solution for Infusion 450 mg/vial (60mg/mL), 7.5ml filled vial b) BI 655130 (Spesolimab), Solution for Injection 300 mg/syringe (150mg/mL), 2ml filled volume c) Matching Placebo BI 655130 (Spesolimab), Solution for Infusion 450 mg/vial (60mg/mL), 7.5ml filled vial 	<ul style="list-style-type: none"> a) Hospital Sultanah Aminah b) Sunway Medical Centre c) Hospital Sultan Ismail d) Hospital Kuala Lumpur e) Hospital Raja Perempuan Zainab II f) Hospital Pulau Pinang g) Hospital Umum Sarawak h) Hospital Sultanah Nur Zahirah 	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			d) Matching Placebo BI 655130 (Spesolimab), Solution for Injection 300 mg/syringe (150mg/mL), 2ml filled volume		
13.	1368-0104	Fasa II/III	<p>a) BI 655130 (Spesolimab), Solution for Infusion 450 mg/vial (60mg/mL), 7.5ml filled vial</p> <p>b) BI 655130 (Spesolimab), Solution for Injection 300 mg/syringe (150mg/mL), 2ml filled volume</p> <p>c) Matching Placebo BI 655130 (Spesolimab), Solution for Infusion 450 mg/vial (60mg/mL), 7.5ml filled vial</p> <p>d) Matching Placebo BI 655130 (Spesolimab), Solution for Injection 300 mg/syringe (150mg/mL), 2ml filled volume</p>	<p>a) Hospital Tunku Azizah</p> <p>b) Sunway Medical Centre</p>	LULUS
14.	WO41554	Fasa III	<p>a) GDC-0077 3mg Tablets</p> <p>b) GDC-0077 9mg Tablets</p> <p>c) Matching Placebo for GDC-0077 3mg Tablets</p> <p>d) Matching Placebo for GDC-0077 9mg Tablets</p> <p>e) Palbociclib 75mg Hard Gelatin Capsules</p> <p>f) Palbociclib 100mg Hard Gelatin Capsules</p> <p>g) Palbociclib 125mg Hard Gelatin Capsules</p> <p>h) Fulvestrant 250mg/5mL Pre-filled Syringes (2 syringes per box)</p>	<p>a) University Malaya Medical Centre</p> <p>b) Sarawak General Hospital</p> <p>c) Institut Kanser Negara</p> <p>d) Hospital Sultan Ismail</p>	LULUS
15.	SLN124-004	Fasa I/II	SLN 124 100 mg/mL, solution for injection	<p>a) Hospital Umum Sarawak</p> <p>b) Hospital Ampang</p> <p>c) Hospital Sultanah Aminah</p> <p>d) Hospital Tengku Ampuan Afzan</p> <p>e) Hospital Sultanah Nur Zahirah</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
16.	64007957MMY3006	Fasa III	<ul style="list-style-type: none"> a) Teclistamab 30mg (10 mg/ml) Liquid in Vial b) Teclistamab 150mg (90 mg/ml) Liquid in Vial c) Velcade (Bortezomib) 3.5mg Powder for Solution for Injection/Infusion d) Carfilzomib 60mg Powder for solution for infusion e) Dexamethasone Oral Tablets 2mg f) Dexamethasone Oral Tablets 8mg g) Dexamethasone Oral Tablets 2mg h) Pomalidomide oral capsules (1 mg) i) Pomalidomide oral capsules (2 mg) j) Pomalidomide oral capsules (3 mg) k) Pomalidomide oral capsules (4 mg) 	<ul style="list-style-type: none"> a) Hospital Queen Elizabeth b) Hospital Pulau Pinang c) Universiti Malaya Medical Centre d) Subang Jaya Medical Centre 	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN MEI 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	22-VIN-0537	Kajian BE	Bisoprolol Hovid 5 mg Tablet	Clinical Site & Bioanalytical Site: Veeda Clinical Research Ltd.	LULUS
2.	22-VIN-0538	Kajian BE	Bisoprolol Hovid 10 mg Tablet	Clinical Site & Bioanalytical Site: Veeda Clinical Research Ltd.	LULUS
3.	IK2294-(01) Apixaban	Kajian BE	TAH3311 Oral Dissolving Film (ODF) 5 mg Eliquis 2.5 mg Film-Coated Tablets	Clinical Site: CRC Research Ward, Sarawak General Hospital Heart Centre Bioanalytical Site: Info Kinetics Sdn. Bhd.	LULUS
4.	20210004	Phase III	Tarlatamab (AMG 757) 1mg/vial Tarlatamab (AMG 757) 10mg/vial IV Solution Stabilizer 10mL/vial	a) Hospital Tengku Ampuan Afzan	LULUS
5.	MK-3475-D46	Phase III	MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial Sacituzumab Govitecan 200mg Lyophilized powder for IV infusion	a) Hospital Pulau Pinang b) Beacon Hospital Sdn Bhd c) Hospital Raja Perempuan Zainab II	LULUS
6.	MK-7902-014	Phase III	Lenvatinib 1 mg Capsule Lenvatinib 4 mg Capsule	a) Sarawak General Hospital b) University Malaya Medical Centre c) Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			Lenvatinib 10 mg Capsule MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial		
7.	61186372PANSC2002 (PolyDamas)	Phase I/ II	JNJ-63723283 Lyophilized Product 240 mg (30 mg/mL), in 8 mL vial JNJ-61186372 350 mg (50 mg/mL), 7 mL solution	a) Hospital Umum Sarawak b) University Malaya Medical Centre	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JUN 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	23-027	Kajian BE	Sunitinib Malate Capsules, 50 mg	Synapse Labs Pvt. Ltd.	LULUS
2.	GARGN-IJZ-1005	Fasa III	GARGN-IJZ 300 U/mL, Solution for Injection in Cartridge	Profil Institut für Stoffwechselforschung GmbH	LULUS
3.	BE. 775/EQL/2022	Kajian BE	Diclofenac Potassium 50mg (Test 1) Diclofenac Potassium 50mg (Test 2)	CRC Research Ward, Sarawak General Hospital Heart Centre	LULUS
4.	D5162C00052	Fasa II	Amivantamab concentrate for solution for infusion 350mg/vial (50 mg/ml) AZD9291 40mg Film-Coated Tablet AZD9291 80mg Film-Coated Tablet	a) Hospital Pulau Pinang b) Hospital Tengku Ampuan Afzan c) Sarawak General Hospital d) University Malaya Medical Centre e) Hospital Raja Perempuan Zainab II f) Hospital Kuala Lumpur	LULUS
5.	MK-1242-036	Fasa II/III	MK-1242 TABLET 2.5MG MK-1242 TABLET 5.0MG MK-1242 TABLET 10.0MG MK-1242 1MG/ML GRANULES MK-1242 PLACEBO TABLET 2.5MG MK-1242 PLACEBO TABLET 5.0MG MK-1242 PLACEBO TABLET 10.0MG MK-1242 PLACEBO 3G GRANULES	a) University Malaya Medical Centre b) Institut Jantung Negara	LULUS
6.	22153	Fasa III	Aflibercept (Bay 86-5321) 114.3 mg/mL solution for injection in a vial Aflibercept (Bay 86-5321) 40 mg/mL (Eylea®) solution for injection in a vial	a) OasisEye Specialists b) Hospital Selayang c) Hospital Shah Alam d) Hospital Al-Sultan Abdullah	LULUS
7.	CNT01959UCO3004	Fasa III	Guselkumab 200mg Prefilled Syringe, 2.0mL	a) University Malaya Medical Centre	

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			Guselkumab 100 mg Prefilled Syringe, 1.0 mL	b) Hospital Sultanah Aminah c) Hospital Tuanku Jaafar	
			Placebo Guselkumab 100 mg Prefilled Syringes, 2.0 mL	d) Hospital Pulau Pinang e) Hospital Selayang	
			Placebo Guselkumab 100 mg Prefilled Syringes, 1.0 mL	f) Hospital Umum Sarawak	
8.	REGEN-016	Fasa III	Single 10mL vial REACT 100x10 ⁶ cells/mL ±20% Suspension for intrarenal injection	a) International Islamic University Malaysia b) Hospital Putrajaya c) University Malaya Medical Centre	LULUS
9.	GGPM-2021-021	Fasa IV	Ceelin Zinc Plus Syrup 120 ml	Hospital Pakar Kanak-Kanak UKM	LULUS
			Matching Placebo for Ceelin Zinc Plus Syrup 120 ml		
10.	ISIS 678354-CS6	Fasa III	0.8mL ISIS 678354 (Olezarsen) solution for Subcutaneous Injection (100 mg/mL) in vials	a) University of Malaya Medical Center b) Hospital Taiping	LULUS
			0.8mL Placebo solution for Subcutaneous Injection (1.5µg/mL Riboflavin, 0.9% sodium chloride) in vials	c) Hospital Sultanah Bahiyah d) Hospital Pulau Pinang	
11.	20220083	Fasa III	ABP 206 240 MG/24ML (10MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION	a) Hospital Universiti Sains Malaysia b) Hospital Umum Sarawak	LULUS
			OPDIVO® (NIVOLUMAB) US 240 MG/24 ML (10 MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION	c) Universiti Kebangsaan Malaysia Medical Centre d) Hospital Pulau Pinang	
			OPDIVO® (NIVOLUMAB) EU 240 MG/24 ML (10 MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION	e) Hospital Kuala Lumpur f) Institut Kanser Negara	
12.	CLOU064F12301	Fasa III	LOU064 (Remibrutinib) 10mg Film-Coated Tablet	Sarawak General Hospital (Dr. Lim Tzyy Huei)	LULUS
			LOU064 (Remibrutinib) 25mg Film-Coated Tablet		
			Matching Placebo to LOU064 (Remibrutinib) 10mg Film-Coated Tablet		

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Matching Placebo to LOU064 (Remibrutinib) 25mg Film-Coated Tablet		
13.	MOM-M281-006	Fasa II/III	Nipocalimab 600mg (30mg/mL), 20mL Solution for intravenous infusion Sodium Chloride 0.9%, 100mL solution for Intravenous infusion	a) Hospital Ampang b) Hospital Umum Sarawak c) University Malaya Medical Centre d) Hospital Tengku Ampuan Afzan e) Hospital Sultanah Aminah f) Sunway Medical Centre g) Hospital Queen Elizabeth	LULUS
14.	9785-CL-0123	Fasa II	Enzalutamide 40mg capsule	Sarawak General Hospital	LULUS
15.	70033093STR3001 70033093ACS3003	Fasa III	JNJ-70033093 (Milvexian) 25mg Film-coated Tablets Matching Placebo for JNJ-70033093 (Milvexian) 25mg	<u>70033093STR3001</u> a) Hospital Universiti Sains Malaysia b) Hospital Kuala Lumpur c) Hospital Sungai Buloh d) Pusat Perubatan Universiti Kebangsaan Malaysia <u>70033093ACS3003</u> a) Sarawak Heart Centre b) Hospital Queen Elizabeth II c) Universiti Teknologi MARA d) Hospital Universiti Sains Malaysia e) Hospital Pulau Pinang f) Hospital Miri g) Pusat Perubatan Universiti Kebangsaan Malaysia	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN JULAI 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	010-23	Kajian BE	Pharmaniaga Metformin UC Tablet 500 mg	Cohance Lifesciences Ltd	LULUS
2.	22-VIN-0218	Kajian BE	Vildagliptin and Metformin Hydrochloride Tablets 50 mg/500 mg	Veeda Clinical Research Ltd.	LULUS
3.	22-VIN-0029	Kajian BE	Vildagliptin and Metformin Hydrochloride Tablets 50 mg/1000 mg	Veeda Clinical Research Ltd.	LULUS
4.	D7020C00001	Fasa I/II	AZD2936 50mg/mL concentrate for solution for infusion, 15mL/vial	(a) University Malaya Medical Centre (b) Hospital Umum Sarawak	LULUS
5.	FURMO-004	Fasa III	Furmonertinib 40mg Tablets	(a) Hospital Raja Perempuan Zainab II (b) Hospital Umum Sarawak (c) Hospital Pulau Pinang (d) Hospital Kuala Lumpur (e) Hospital Canselor Tuanku Muhriz UKM	LULUS
			Pemetrexed for injection for intravenous infusion 500mg, 20mL in a vial		
			Carboplatin injection for intravenous infusion 600mg, 60mL in a vial		
			Cisplatin injection for intravenous infusion 100mg, 100mL in a vial		
6.	BGB-A317-A445-101	Fasa I	BGB-A445 200 mg/10mL Concentrate for solution for infusion	(a) Hospital Umum Sarawak (b) University Kebangsaan Malaysia Medical Centre (c) University Malaya Medical Centre	LULUS
			BGB-A317 100 mg/10 mL Concentrate for solution for infusion		
7.	70033093AFL3002	Fasa III	JNJ-70033093 (Milvexian) 100mg Tablet (70 Tablets per Bottle)	(a) Hospital Tengku Ampuan Afzan (b) Hospital Seri Manjung (c) Hospital Taiping (d) Hospital Queen Elizabeth II (e) Hospital Sultanah Bahiyah (f) Hospital Universiti Sains Malaysia (g) Hospital UiTM Puncak Alam (h) Institut Jantung Negara	LULUS
			Matching Placebo for JNJ-70033093 (Milvexian) 100 mg Tablet		
			Apixaban 5mg Capsules (70 Capsules per Bottle)		
			Apixaban 2.5mg Capsules (70 Capsules per Bottle)		
			Matching Placebo for Apixaban 5mg Capsules (70 Capsules per Bottle)		
			Matching Placebo for Apixaban 2.5mg Capsules (70 Capsules per Bottle)		

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			Apixaban 5mg Tablets (60 Tablets per Bottle)		
			Apixaban 2.5mg Tablets (60 Tablets per Bottle)		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OGOS 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BE.798/EQL/2023	Kajian BE	Bisoprolol Fumarate Tablet 5mg	PT Equilab International	LULUS
2.	BX-BE23-AMP-003	Kajian BE	Cynpamax Film Coated Tablet 100mg	Clinical Research Ward, Hospital Ampang	LULUS
3.	C1B03281	Kajian BE	Deferiprone Tablets 500 mg	Cliantha Research Limited	LULUS
4.	D7000C00001	Fasa I/III	AZD3152 150mg/mL, 2mL labelled vial	(a) Hospital Umum Sarawak	LULUS
			AZD1061 100mg/mL, 1.5mL labelled vial	(b) Hospital Seberang Jaya	
			AZD8895 100mg/mL, 1.5mL labelled vial	(c) Pusat Perubatan Universiti Kebangsaan Malaysia (d) University Malaya Medical Centre (e) Sunway Medical Centre	
5.	CHK01-03	Fasa II	Atrasentan Tablet 0.75mg	(a) University Malaya Medical Centre	LULUS
			Matching Placebo Tablet for Atrasentan 0.75mg	(b) Hospital Raja Permaisuri Bainun	
6.	TO-01C101	Fasa I	TO-O-1001, Ophthalmic Solution, 0.1%	(a) Sarawak General Hospital	LULUS
			TO-O-1001 Placebo, Ophthalmic Solution, 0.1%	(b) Hospital Tengku Ampuan Rahimah	
7.	XL092-304	Fasa III	XL092 Tablet 40 mg	(a) Hospital Kuala Lumpur	LULUS
			XL092 Tablet 60 mg	(b) University Malaya Medical Centre	
			XL092 Tablet 100 mg	(c) Institut Kanser Negara	
			Sunitinib Malate 12.5 mg Capsules		
			Sunitinib Malate 25 mg Capsules		
			Nivolumab Concentrate for Solution for Infusion, 10 mg/mL		

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	MK-8591A-053	Fasa III	MK-8591A 100mg / 0.25mg (MK-1439 100mg + MK-8591 0.25mg) film coated tablet	(a) Sarawak General Hospital (b) Hospital Kuala Lumpur (c) Hospital Selayang (d) Hospital Sultanah Bahiyah (e) Hospital Sungai Buloh (f) Hospital Pulau Pinang (g) University Malaya Medical Centre	LULUS
		Bictegravir 50mg / Emtricitabine 200mg / Tenofovir Alafenamide 25mg film-coated tablet			
		Placebo to MK-8591A 100mg / 0.25mg (MK-1439 100mg + MK-8591 0.25mg) film coated tablet			
		Placebo to Bictegravir 50mg / Emtricitabine 200mg / Tenofovir Alafenamide 25mg film-coated tablet			

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	D8531C00002	Fasa III	AZD9833 Film-coated Tablet 75 mg	(a) Hospital Wanita dan Kanak-Kanak Sabah	LULUS
			Anastrozole Film-coated Tablet 1 mg	(b) Hospital Sultan Ismail	
			Letrozole Film-coated Tablet 2.5 mg	(c) Penang Adventist Hospital	
			Exemestane Film-coated Tablet 25 mg	(d) Hospital Universiti Sains Malaysia	
			Tamoxifen Film-coated Tablet 20 mg	(e) University Malaya Medical Centre (f) Hospital Kuala Lumpur (g) Mahkota Medical Centre	
2.	D5982C00005	Fasa III	Metered Dose Inhaler (MDI) Pressurized Inhalation Suspension budesonide/ formoterol fumarate 80/4.8 µg per actuation, 120 actuations	(a) Hospital Miri	LULUS
			Metered Dose Inhaler (MDI) Pressurized Inhalation Suspension budesonide (BD), 80 µg per actuation, 120 actuations	(b) University Malaya Medical Centre (c) Hospital Raja Permaisuri Bainun (d) Hospital Pulau Pinang (e) Hospital Serdang	
			BFF/BD MDI Placebo (for training)		
3.	Version 1.00 / 27.07.22	Fasa IV	Mupirocin Cream USP 2% (15g)	Hospital Canselor Tuanku Muhriz UKM (HCTM)	LULUS
4.	F7TG2202	Fasa III	LR769 - eptacog-beta (activated) 5mg/vial, 1mg/mL after reconstitution, powder for solution for injection	(a) Hospital Queen Elizabeth (b) Hospital Ampang	LULUS
			Sterile Water for Injection – 5.2 ml pre-filled syringe, intravenous		
5.	D9604C00001	Fasa III	Andexanet Alfa Powder for Solution for Infusion 200 mg/vial	(a) Hospital Queen Elizabeth (b) International Islamic University Malaysia	LULUS
6.	NN1436-4910	Fasa III	Insulin Icodec 700U/mL Solution for Injection, 3mL pre-filled pen-injector	(a) Hospital Miri	LULUS
			Semaglutide 1.34mg/mL in 1.5mL pre-filled PDS290 pen-injector	(b) Hospital Putrajaya (c) Universiti Teknologi MARA (UiTM) (d) Hospital Universiti Kebangsaan Malaysia	
7.	BRII-835-002	Fasa II	Vial containing 0.5 mL BRII-835 (VIR-2218) at 200 mg/ mL, Solution for Subcutaneous Injection	(a) Hospital Queen Elizabeth (b) Hospital Sultanah Bahiyah (c) Sarawak General Hospital	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			Pre-filled Syringe of Peginterferon alfa-2a 180mcg/0.5mL, Solution for Injection	(d) University Malaya Medical Centre (e) Hospital Sultanah Aminah	
			Pre-filled Syringe of Peginterferon alfa-2a 135mcg/0.5mL, Solution for Injection		
8.	DMX-200-301	Fasa III	DMX-200 (repagermanium) 120 mg Capsule	(a) Hospital Tengku Ampuan Afzan	LULUS
			Matching Placebo for DMX-200 (repagermanium) 120 mg Capsule		

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OKTOBER 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BCX10013-105	Fasa Ib	BCX10013, 50 mg capsules	Hospital Ampang	LULUS BERSYARAT
			BCX10013, 80 mg capsules		
			Meningococcal Group B Vaccine Trumenba®, 0.5mL Prefilled Syringe		
			PNEUMOVAX® 23 Pneumococcal Vaccine Polyvalent solution, 0.5 mL single-dose vial		
			HIBERIX [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) solution for injection, 0.5mL single-dose vial for intramuscular injection		
			PREVNAR 20 (Pneumococcal 20-valent Conjugate Vaccine), 0.5mL pre-filled syringe, suspension for intramuscular injection		
			MenQuadfi®, Meningococcal (Groups A, C, Y, W) Conjugate Vaccine, 0.5mL solution in a single-dose vial for intramuscular injection		
2.	R1979-HM-2299 R1979-ONC-2105 R1979-ONC-22102	Fasa III	1mL of 2mg/mL of Odronextamab (REGN1979) liquid solution in 2mL vial	(a) Hospital Tengku Ampuan Afzan (b) Hospital Queen Elizabeth (c) Hospital Ampang (d) University Malaya Medical Centre (e) Subang Jaya Medical Center (f) Hospital Sultanah Aminah	LULUS
			8mL of 20mg/mL of Odronextamab (REGN1979) liquid solution in 10mL vial		
3.	RLY5016-208p	Fasa II	Patiromer 1 g, Powder for Oral Suspension	(a) University Malaya Medical Centre (b) Hospital Umum Sarawak (c) Sunway Medical Centre (d) Hospital Tunku Azizah	LULUS
			Patiromer Sorbitex Calcium 2 g		
4.	KZR-616-202	Fasa IIb	Single dose 60 mg/vial of Zetomipzomib (KZR-616) powder for solution for injection	(a) Hospital Tengku Ampuan Afzan (b) Hospital Sultan Idris Shah Serdang (c) Hospital Selayang (d) Hospital Raja Permaisuri Bainun (e) Prince Court Medical Centre (f) Hospital Canselor Tuanku Muhriz UKM (g) Universiti Malaya Medical Centre (h) Hospital Al Sultan Abdullah	LULUS
			Single dose 60 mg/vial of placebo for Zetomipzomib (KZR-616) powder for solution for injection		
			Mycophenolate mofetil 500mg film-coated tablets		

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
5.	77242113UCO2001	Fasa IIb	JNJ-77242113 100 mg Film-coated Tablet	(a) University Malaya Medical Centre (b) Hospital Sultanah Aminah (c) Sultan Idris Shah Hospital	LULUS
			JNJ-77242113 200 mg Film-coated Tablet		
			JNJ-77242113 Placebo 100 mg Film-coated Tablet		
			JNJ-77242113 Placebo 200 mg Film-coated Tablet		
6.	22-VIN-0211	BE	Vildagliptin 50 mg Tablet	Clinical & Bioanalytical site: Veeda Clinical Research Ltd.	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN NOVEMBER 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	GS-US-592-6173	Fasa III	Sacituzumab Govitecan Lyophilized Powder for Solution for Infusion, 200 mg	(a) Hospital Sultan Ismail (b) Hospital Umum Sarawak (c) Hospital Kuala Lumpur (d) Institut Kanser Negara	LULUS
			Pembrolizumab Concentrate for Solution for Infusion, 25 mg/mL		
			Nab-Paclitaxel 5 mg/mL Powder for Dispersion for Infusion		
			Paclitaxel Concentrate for Solution for Infusion, 6 mg/mL in 16.7 mL		
			Carboplatin Concentrate for Solution for Infusion, 10 mg/mL		
2.	GS-US-592-6238	Fasa III	Sacituzumab Govitecan Lyophilized Powder for Solution for Infusion, 200 mg	(a) Hospital Sultan Ismail (b) Hospital Umum Sarawak (c) Hospital Kuala Lumpur (d) Institut Kanser Negara	LULUS
			Nab-Paclitaxel 5 mg/mL Powder for Dispersion for Infusion		
			Paclitaxel Concentrate for Solution for Infusion, 6 mg/mL in 16.7 mL		
			Carboplatin Concentrate for Solution for Infusion, 10 mg/mL		
3.	D6970C00002	Fasa III	Baxdrostat 1 mg tablet	(a) Hospital Miri (b) Hospital Melaka (c) Hospital Seri Manjung (d) Hospital Sultan Idris Shah Serdang (e) Hospital Pakar Sultanah Fatimah (f) Hospital Umum Sarawak (g) Hospital Raja Perempuan Zainab II	LULUS
			Baxdrostat 2 mg tablet		
			Placebo for baxdrostat tablet		
4.	CHK02-02	Fasa III	BION-1301 300 mg/2mL (150mg/mL) solution for injection in Pre-Filled Syringes	(a) Hospital Kuala Lumpur (b) Hospital Sultan Idris Shah Serd (c) University Malaya Medical Centre (d) Hospital Sibul	LULUS
			BION-1301 Placebo solution for injection 2mL in Pre-Filled Syringes		
5.	D8210C00003	Fasa IIa	60 doses of AZD4604 0.2 mg inhalation powder. SD3FL inhaler	(a) University Malaya Medical Centre (b) Hospital Raja Perempuan Zainab II	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			60 doses of AZD4604 1 mg inhalation powder. SD3FL inhaler	(c) Hospital Sultan Idris Shah Serdang	
			60 doses of Placebo inhalation powder. SD3FL inhaler		
6.	D5087C00001	Fasa IIb	Savolitinib 100mg Film-coated Tablet	(a) Hospital Raja Perempuan Zainab II (b) Hospital Wanita dan Kanak-Kanak Sabah	LULUS
			Osimertinib 40mg Film-coated Tablet		
			Osimertinib 80mg Film-coated Tablet		
7.	20190341	Fasa III	Sotorasib (AMG 510) 120mg Film-Coated Tablet Pembrolizumab 25 mg/mL concentrate for solution for infusion	(a) University Malaya Medical Centre (b) Hospital Tengku Ampuan Afzan (c) Pantai Hospital Kuala Lumpur	LULUS
8.	NN7769-4532	Fasa IIIb	NNC0365-3769 B 2.0mg/mL Solution for Injection in 0.8 mL pen-injector	(a) Hospital Ampang (b) Hospital Queen Elizabeth	LULUS
			NNC0365-3769 B 5.0mg/mL Solution for Injection in 0.8 mL pen-injector		
			NNC0365-3769 B 11.3mg/mL Solution for Injection in 0.8 mL pen-injector		
			NNC0365-3769 B 25.0mg/mL Solution for Injection in 0.8 mL pen-injector		
			NNC0365-3769 B 57.5mg/mL Solution for Injection in 0.8 mL pen-injector		
9.	D5180C00024	Fasa III	1 pre-filled syringe 1.91 mL Tezepelumab Solution for injection 110 mg/mL	(a) University Malaya Medical (b) Hospital Pulau Pinang (c) Hospital Raja Perempuan Zainab II	LULUS
			1 pre-filled syringe 1.91 mL Placebo solution for injection		
10.	CLOU064A2304	Fasa IIIb	Omalizumab 150 mg/1 ml Solution for Injection in Pre-filled Syringe	(a) Hospital Pulau Pinang (b) Hospital Raja Permaisuri Bainu (c) Hospital Pakar Sultanah Fatimah (d) Hospital Putrajaya (e) Hospital Kuala Lumpur	LULUS
			Omalizumab Placebo 1 ml Solution for Injection in Pre-filled Syringe		
			LOU064 (Remibrutinib) 25 mg Film-Coated Tablet		
			Matching Placebo to LOU064 (Remibrutinib) 25 mg Film-Coated Tablet		

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
11.	OP-1250-301	Fasa III	OP-1250 Film-coated Tablets 30mg	(a) Sarawak General Hospital (b) Institut Kanser Negara (c) Beacon Hospital (d) Hospital Pulau Pinang (e) Hospital Raja Permaisuri Bainun (f) Hospital Universiti Sains Malaysia (g) Pantai Hospital Sungai Petani	LULUS
			OP-1250 Film-coated Tablets 60mg		
12.	C1B03126	Kajian BE	Everolimus Tablets 5mg	Cliantha Research Limited	LULUS
13.	C1B03127	Kajian BE	Everolimus Tablets 5mg	Cliantha Research Limited	LULUS
14.	BE23-001	Kajian BE	NicePower F.C Tablet 20 mg	Questa Bio-Clinical Research Centre	LULUS

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN DISEMBER 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BE23-006	Kajian BE	Duocetz (Tramadol HCL 37.5mg + Paracetamol 325 mg Tablets)	Questra Clinical Research Sdn Bhd	LULUS
2.	BE23-003	Kajian BE	Mirtazapine Orodispersible Tablet 30 mg	Questra Clinical Research Sdn Bhd	LULUS
3.	BX-BE23-AMP-005	Kajian BE	Voxyzine Film Coated Tablet 25mg	Clinical Research Ward, Ampang, Selangor Bioxis Sdn. Bhd., Pulau Pinang.	LULUS
			Atarax Film Coated Tablet 25mg		
4.	AT-01B-004	Fasa II	AT-527 (Bemnifosbuvir) 275mg Tablets	a) Hospital Selayang b) Hospital Universiti Sains Malaysi c) Hospital Raja Perempuan Zainab II d) Hospital Universiti Kebangsaan Malaysia e) Hospital Queen Elizabeth f) Hospital Serdang	LULUS
			AT-038 (Ruzasvir) 90mg Capsules		
5.	D9180C00012	Fasa III	2 mL pre-filled syringe Tozorakimab (MEDI3506) solution for injection 150 mg/mL	a) University Malaya Medical Centre b) Hospital Raja Perempuan Zainab II c) Hospital Sultan Idris Shah (Hospital Serdang) d) Hospital Tuanku Ja'afar e) Hospital Miri	LULUS
			Placebo for 2 mL pre-filled syringe Tozorakimab (MEDI3506) solution for injection 150 mg/mL		
6.	GCT3014-01	Fasa I/II	GEN3014 (Hexabody-CD38) 20 mg/mL Concentrate 20 mL per Vial	a) Beacon Hospital b) Hospital Ampang c) Hospital Sultanah Aminah d) Hospital Umum Sarawak	LULUS
			DARZALEX 1800 mg Solution for Injection in 15mL Vial, 120mg/mL		
7.	61186372NSC2007	Fasa II	JNJ-61186372 350mg (50mg/mL), 7mL Solution	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Hospital Tengku Ampuan Afzan d) Hospital Umum Sarawak	LULUS
			Lazertinib 80mg tablet		
			Chlorhexidine Gluconate 4.0% w/v 946mL Solution		
			Clindamycin Phosphate 1% w/v (10mg), 30mL Cutaneous Emulsion		
			Doxycycline 100mg Tablet		
			Minocycline 100 mg Capsule		
8.	202009	Fasa III	GSK3228836 Solution for Injection 150mg/mL in 1mL vial	a) Hospital Sultanah Aminah b) Hospital Tengku Ampuan Afzan c) Hospital Pulau Pinang d) Hospital Queen Elizabeth	LULUS
			Sodium Chloride (0.9% NaCl) in 10mL ampoule		

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
				e) University Malaya Medical Centre f) Hospital Universiti Sains Malaysia	
9.	219288	Fasa III	GSK3228836 Solution for Injection 150mg/mL 1mL per vial Sodium Chloride (0.9% NaCl) 10mL per ampoule	a) Hospital Sultanah Nur Zahirah b) Hospital Queen Elizabeth c) Hospital Tengku Ampuan Afzan d) Hospital Sultanah Aminah e) University Malaya Medical Centre f) Hospital Universiti Sains Malaysia	LULUS
10.	JW21301	Fasa III	Epaminurad Tablet 6 mg Epaminurad Tablet 9 mg Febuxostat Tablet 40 mg Febuxostat Tablet 80 mg Epaminurad Tablet 6 mg Placebo Epaminurad Tablet 8 mg Placebo Febuxostat Tablet 40 mg Placebo Febuxostat Tablet 80 mg Placebo	a) University Malaya Medical Centre b) Universiti Kebangsaan Malaysia Medical Centre c) Sarawak General Hospital d) Hospital Selayang e) Hospital Tuanku Ja'afar f) Hospital Pakar Sultanah Fatimah	LULUS
11.	CEYU688A12201	Fasa II	EYU688 100 mg Hard Gelatin Capsule Matching Placebo to EYU688 100 mg Hard Gelatin Capsule	a) Hospital Miri b) Sultan Ahmad Shah Medical Centre c) Hospital Seberang Jaya d) Hospital Queen Elizabeth II	LULUS
12.	EBCT003	Fasa III	Nuvastatic effervescent Powder 1000mg of standardized extract of Orthosiphon Stamineus Matching Placebo for Nuvastatic effervescent Powder	Pusat Perubatan Mahkota	TOLAK
13.	GS-US-598-6168	Fasa III	Sacituzumab Govitecan Lyophilized Powder for Solution for Infusion, 200 mg Paclitaxel Concentrate for Solution for Infusion, 6 mg/mL in 16.7 mL Nab-Paclitaxel 5 mg/mL Powder for Dispersion for Infusion Capecitabine 150 mg film-coated tablets Capecitabine 500 mg film-coated tablets	a) Sarawak General Hospital b) Institut Kanser Negara c) Hospital Kuala Lumpur d) University Malaya Medical Centre (UMMC)	LULUS