

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2020

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	GlimicronMR60Fasted-Hovid	Kajian BE	1) Glimicron MR 60 mg Tablet	1) Clinical Research Ward, Hospital Ampang	Lulus
2.	21406	Kajian BE	1) 1613932 2) 1611958	1) Info Kinetics Sdn Bhd	Lulus
3.	CMBG453B12301	Fasa III	1) MBG453 400mg/4mL (Concentrate for Solution for Infusion) 2) Placebo to MBG453 400mg/4mL	1) Hospital Ampang 2) Hospital Pulau Pinang 3) Hospital Umum Sarawak 4) Pusat Perubatan Universiti Malaya	Lulus
4.	VIS649-201	Fasa II	1) VIS649 Solution for Infusion (25mg/mL)	1) Hospital Canselor Tuanku Muhriz UKM 2) Hospital Tuanku Ja'afar Seremban 3) Hospital Tengku Ampuan Rahimah 4) Hospital Tengku Ampuan Afzan 5) University Malaya Medical Centre	Lulus

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
5.	REVC003	Fasa Ila	<ol style="list-style-type: none"> 1) RV521 10mg Capsule 2) RV521 20mg capsule 3) RV521 50mg capsule 4) RV521 Placebo Capsule (Size 3) 5) RV521 Placebo Capsule (Size 0) 6) Dextrose Gel 40% 80g 	<ol style="list-style-type: none"> 1) Hospital Raja Perempuan Zainab II 2) Hospital Seberang Jaya 3) Hospital Sultanah Nur Zahirah 4) Hospital Raja Permaisuri Bainun 5) Hospital Taiping 6) Hospital Umum Sarawak 7) Hospital Seri Manjung 8) Hospital Sibul 	Lulus
6.	IMR-BTL-201	Fasa II	<ol style="list-style-type: none"> 1) Tablets of 100mg IMR-687 2) Tablets of 150mg IMR-687 3) Tablets of 200mg IMR-687 4) Placebo Tablet to match Tablet of 100mg/150mg/200mg IMR-687 	<ol style="list-style-type: none"> 1) Hospital Umum Sarawak 2) Hospital Pulau Pinang 3) Hospital Raja Permaisuri Bainun 4) Hospital Sultanah Aminah 5) Hospital Queen Elizabeth 6) Hospital Sultanah Bahiyah 	Lulus
7.	TRACK	Fasa III	<ol style="list-style-type: none"> 1) Rivaroxaban 2.5mg film-coated tablet 2) Placebo for Rivaroxaban 2.5mg film-coated tablet 	<ol style="list-style-type: none"> 1) Hospital Tuanku Ja'afar Seremban 2) Hospital Kajang 3) Hospital Raja Permaisuri Bainun 4) Universiti Malaya Medical Centre 5) Hospital Seberang Jaya 6) Hospital Canselor Tunku Muhkriz UKM 7) Hospital Queen Elizabeth 	Lulus

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8.	PO-CL-MM-PI-005779 (AMN003)	Fasa III	<ol style="list-style-type: none"> 1) Pomalidomide 2 mg capsules 2) Pomalidomide 3 mg capsules 3) Pomalidomide 4 mg capsules 	<ol style="list-style-type: none"> 1) University Malaya Medical Centre 2) Ramsay Sime Darby Healthcare (RSDH) Subang Jaya 3) Hospital Ampang 	Lulus
9.	54135419TRD3013	Fasa III	<ol style="list-style-type: none"> 1) Quetiapine Prolonged-Release Film-Coated 50mg Tablet 2) Quetiapine Prolonged-Release Film-Coated 150mg Tablet 3) Quetiapine Prolonged-Release Film-Coated 300mg Tablet 4) Esketamine 14% Intranasal Spray Solution, 0.2mL 5) Esketamine Training Device 	<ol style="list-style-type: none"> 1) University Malaya Medical Centre 	Lulus
10.	OWC120YKL	Fasa IIa	<ol style="list-style-type: none"> 1) WF10: 0.1 g OXO-K993 per 1 mL Solution – 20 mL per vial for infusion 	<ol style="list-style-type: none"> 1) Hospital University Kebangsaan Malaysia 	Lulus
11.	178-CL-204	Fasa III	<ol style="list-style-type: none"> 1) Mirabegron 25mg Prolonged-release Tablet 2) Mirabegron 50mg Prolonged-release Tablet 3) Mirabegron 830mg Granules for Oral Suspension 4) Matching Placebo for Mirabegron 25mg Prolonged-release Tablet 5) Matching Placebo for Mirabegron 50mg Prolonged-release Tablet 	<ol style="list-style-type: none"> 1) University Malaya Medical Centre 2) Hospital Kuala Lumpur 3) Hospital Pulau Pinang 	Lulus

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
			6) Matching Placebo for Mirabegron 830mg Granules for Oral Suspension		