

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 |

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| 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 |

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| | | | <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 |

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| | | | d) Matching Placebo BI 655130 (Spesolimab), Solution for Injection 300 mg/syringe (150mg/mL), 2ml filled volume | | |
| 13. | 1368-0104 | Fasa II/III | 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 d) Matching Placebo BI 655130 (Spesolimab), Solution for Injection 300 mg/syringe (150mg/mL), 2ml filled volume | a) Hospital Tunku Azizah b) Sunway Medical Centre | LULUS |
| 14. | WO41554 | Fasa III | a) GDC-0077 3mg Tablets b) GDC-0077 9mg Tablets c) Matching Placebo for GDC-0077 3mg Tablets d) Matching Placebo for GDC-0077 9mg Tablets e) Palbociclib 75mg Hard Gelatin Capsules f) Palbociclib 100mg Hard Gelatin Capsules g) Palbociclib 125mg Hard Gelatin Capsules h) Fulvestrant 250mg/5mL Pre-filled Syringes (2 syringes per box) | a) University Malaya Medical Centre b) Sarawak General Hospital c) Institut Kanser Negara d) Hospital Sultan Ismail | LULUS |
| 15. | SLN124-004 | Fasa I/II | SLN 124 100 mg/mL, solution for injection | a) Hospital Umum Sarawak b) Hospital Ampang c) Hospital Sultanah Aminah d) Hospital Tengku Ampuan Afzan e) Hospital Sultanah Nur Zahirah | LULUS |

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| 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 |