

**STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN NOVEMBER 2021**

| <b>Bil.</b> | <b>No. Protokol</b> | <b>Fasa Kajian Klinik</b> | <b>Nama Produk</b>        | <b>Pusat Kajian Klinik</b>  | <b>Status Permohonan</b> |
|-------------|---------------------|---------------------------|---------------------------|---|--------------------------|
| 1.          | 0327-21             | Kajian BE                 | Eltrombopag Tablets 75 mg | <p>Clinical Site:<br/>Lambda Therapeutic Research Ltd<br/>Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India<br/>(Dr. Poojan Patel)</p> <p>Bioanalytical Site:<br/>Lambda Therapeutic Research Ltd<br/>Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India</p> | LULUS                    |
| 2.          | 0328-21             | Kajian BE                 | Eltrombopag Tablets 75 mg | <p>Clinical Site:<br/>Lambda Therapeutic Research Ltd<br/>Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad - 382481, India<br/>(Dr. Poojan Patel)</p> <p>Bioanalytical Site:<br/>Lambda Therapeutic Research Ltd<br/>Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota,</p>                           | LULUS                    |

| Bil. | No. Protokol | Fasa Kajian Klinikal | Nama Produk                                  | Pusat Kajian Klinikal   | Status Permohonan |
|------|--------------|----------------------|--|---|-------------------|
|      |              |                      |  | Ahmedabad - 382481, India   |                   |
| 3.   | 0333-21      | Kajian BE            | Telmisartan and Amlodipine tablets 80mg/10mg | <p>Clinical Site:<br/> Lambda Therapeutic Research Ltd<br/> Lambda House, Plot No. 38, Survey No. 388, Near<br/> Solver Oak Club, S.G. Highway, Gota, Ahmedabad -<br/> 382481, India<br/> (Dr. Poojan Patel)</p> <p>Bioanalytical Site:<br/> Lambda Therapeutic Research Ltd<br/> Lambda House, Plot No. 38, Survey No. 388, Near<br/> Solver Oak Club, S.G. Highway, Gota, Ahmedabad -<br/> 382481, India</p>        | LULUS             |
| 4.   | 2020-BE-005  | Kajian BE            | hovid-Clofenac 50 mg Enteric Coated Tablet   | <p>Clinical Site:<br/> Clinical Research Ward<br/> Clinical Trial Unit,<br/> Level 7, Hospital Ampang,<br/> Jalan Mewah Utara, Pandan Mewah,<br/> 68000 Ampang, Selangor<br/> (Dr. Damenthi Nair A/P Narayanan)</p> <p>Bioanalytical Site:<br/> BA/BE Laboratory<br/> Attest Research Sdn. Bhd.<br/> Lot 16030, Plot 88G, Lintang Bayan Lepas 10,<br/> Kawasan Perindustrian Bayan Lepas,<br/> 11900 Bayan Lepas,</p> | LULUS             |

| Bil. | No. Protokol  | Fasa Kajian Klinik | Nama Produk   | Pusat Kajian Klinik   | Status Permohonan |
|------|---------------|--------------------|---|---|-------------------|
|      |               |                    |   | Pulau Pinang  |                   |
| 5.   | NN1535-4593   | Fasa III           | <ul style="list-style-type: none"> <li>a) IcoSema 700U/mL + 2mg/mL, solution for injection, 1.5 ml prefilled pen-injector</li> <li>b) Insulin Glargine 100U/mL, solution for injection, 3mL prefilled pen-injector</li> <li>c) Insulin Aspart 100U/mL, solution for injection, 3ml prefilled pen-injector</li> </ul>  | <ul style="list-style-type: none"> <li>a) University Malaya Medical Centre (UMMC)</li> <li>b) Hospital Miri</li> <li>c) Klinik Kesihatan Simpang Kuala</li> <li>d) Hospital Universiti Sains Malaysia (HUSM)</li> <li>e) University Technology MARA (UiTM)</li> <li>f) Universiti Kebangsaan Malaysia Medical Centre, Kuala Lumpur (UKMMC)</li> </ul> | LULUS             |
| 6.   | CLOU064A2302  | Fasa III           | <ul style="list-style-type: none"> <li>a) LOU064 (Remibrutinib) 25mg Film-Coated Tablet</li> <li>b) Matching Placebo to LOU064 (Remibrutinib) 25mg Film-Coated Tablet</li> </ul>  | <ul style="list-style-type: none"> <li>a) Hospital Putrajaya</li> <li>b) Hospital Pakar Sultanah Fatimah</li> <li>c) Hospital Pulau Pinang</li> <li>d) Hospital Kuala Lumpur</li> <li>e) Hospital Raja Permaisuri Bainun</li> </ul>   | LULUS             |
| 7.   | CDRB436J12301 | Fasa III           | <ul style="list-style-type: none"> <li>a) DRB436 (DABRAFENIB) 50mg Hard Non-Gelatin Capsule</li> <li>b) DRB436 (DABRAFENIB)75 mg Hard Non-Gelatin Capsule</li> <li>c) TMT212 (TRAMETINIB) 0.5 mg Film Coated Tablet</li> <li>d) TMT212 (TRAMETINIB) 2 mg Film Coated Tablet</li> <li>e) Placebo to DRB436 (DABRAFENIB) 50mg Hard non-gelatin capsule</li> <li>f) Placebo to DRB436 (DABRAFENIB) 75mg Hard non-gelatin capsule</li> <li>g) Placebo to TMT212 (TRAMETINIB) 0.5mg Film Coated Tablets</li> </ul> | <ul style="list-style-type: none"> <li>i) Hospital Kuala Lumpur</li> <li>j) Hospital Pulau Pinang</li> <li>k) Pantai Hospital Kuala Lumpur</li> <li>l) University Malaya Medical Centre</li> </ul>  | LULUS             |

| Bil. | No. Protokol | Fasa Kajian Klinik | Nama Produk   | Pusat Kajian Klinik   | Status Permohonan |
|------|--------------|--------------------|---|---|-------------------|
|      |              |                    | h) Placebo to TMT212 (TRAMETINIB) 2mg Film Coated Tablets |   |                   |
| 8.   | 8.0          | Fasa II            | S-649266 powder for solution for infusion 1g/vial         | a) University Malaya Medical Centre<br>b) Universiti Sains Malaysia Health Campus | LULUS             |
| 9.   | MK-4482-013  | Fasa III           | a) MK-4482 200mg capsules<br>b) MK-4482 Placebo capsules  | a) Hospital Raja Perempuan Zainab II<br>b) Klinik Kesihatan Masjid Tanah          | LULUS             |