

**STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN FEBRUARI 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.	BX-BE20-AMP-004	Kajian BE	Lexib Capsule 200mg	<p><b>Clinical Site:</b> Clinical Research Ward Clinical Trial Unit, Level 7, Hospital Ampang, Jalan Mewah Utara, Pandan Mewah, 68000 Ampang, Selangor</p> <p><b>Bioanalytical Site:</b> Bioxis Sdn Bhd Plot 301(b), Jalan Perindustrian Bukit Minyak 8 Taman Perindustrian Bukit Minyak 14100 Simpang Ampat Pulau Pinang</p>	LULUS
2.	BE18-001	Kajian BE	<p>a) Purinetone Tablet 50mg b) Mercaptopurine Tablet 50mg</p>	<p><b>Clinical site:</b> Institut Perubatan &amp; Pergigian Termaju (IPPT) Universiti Sains Malaysia, Bertam, 13200 Kepala Batas, Pulau Pinang</p> <p><b>Bioanalytical site:</b> Questra Bio-Clinical Research Centre Questra Clinical Research Sdn. Bhd. No. 6, Jalan Desa Pauh, Taman Desa Pauh 13700 Permatang Pauh, Pulau Pinang.</p>	LULUS
3.	21597	Kajian BE	a) UI 1614605 – Naproxen Sodium 220 mg Soft Gelatin Capsule	<p><b>Clinical site and bioanalytical site:</b> Info Kinetics Sdn Bhd</p>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			b) UI 1600169 – Naproxen Sodium 220 mg Tablet	5th floor, Gleneagles Penang, No.1 Jalan Pangkor, 10050 Pulau Pinang.	
4.	21598	Kajian BE	a) UI 1614605 – Naproxen Sodium 220 mg Soft Gelatin Capsule b) UI 1600169 – Naproxen Sodium 220 mg Tablet	<b>Clinical site and bioanalytical site:</b> Info Kinetics Sdn Bhd 5th floor, Gleneagles Penang, No.1 Jalan Pangkor, 10050 Pulau Pinang.	LULUS
5.	42847922MDD3005	Fasa III	a) JNJ-42847922 20mg Capsule b) Quetiapine 50mg Capsule c) Quetiapine 150mg Capsule d) Matching Placebo for Seltorexant 20mg, quetiapine 50mg and quetiapine 150mg Capsule	a) Hospital Tuanku Jaafar b) Hospital Permai c) Hospital Raja Permaisuri Bainun	LULUS
6.	CRTH258A2303E1	Fasa IIIb/IV	a) Brolocizumab (RTH258) 6mg/0.05mL solution for injection in prefilled syringe b) Brolocizumab (RTH258) 6mg/0.05mL solution for injection	a) Hospital Shah Alam b) Hospital Selayang c) Southern Specialist Eye Centre	LULUS
7.	APD334-202	Fasa II/III	a) Etrasimod 1mg Tablet b) Etrasimod 2mg Tablet c) Etrasimod Placebo Tablet	a) University Malaya Medical Centre b) Hospital Tengku Ampuan Rahimah c) Hospital Universiti Sains Malaysia	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
8.	CLNP023A2301	Fasa III	<ul style="list-style-type: none"> <li>a) LNP023 200 mg hard gelatin capsule</li> <li>b) Matching Placebo for LNP023 200 mg hard gelatin capsule</li> </ul>	<ul style="list-style-type: none"> <li>a) Hospital Kuala Lumpur</li> <li>b) University Malaya Medical Centre</li> </ul>	LULUS
9.	53718678RSV3001	Fasa III	<ul style="list-style-type: none"> <li>a) JNJ-53718678-ZCL eq. 217.4 mg/g Powder for Suspension/Bottle</li> <li>b) Placebo to JNJ-53718678-ZCL</li> <li>c) JNJ-53718678-ZCL Solvent 19.4mL</li> </ul>	<ul style="list-style-type: none"> <li>a) Hospital Miri</li> <li>b) Hospital Selayang</li> <li>c) Hospital Sibul</li> <li>d) Hospital Taiping</li> <li>e) Hospital Wanita dan Kanak-kanak Sabah</li> <li>f) Hospital Bintulu</li> </ul>	LULUS
10.	CKJX839C12301	Fasa III	<ul style="list-style-type: none"> <li>a) Inclisiran (KJX839) sodium 300 mg (equivalent to 284 mg Inclisiran) in 1.5 mL solution for injection in pre-filled syringe</li> <li>b) Placebo to Inclisiran (KJX839) sodium 300 mg (equivalent to 284 mg Inclisiran) in 1.5 mL solution for injection in pre-filled syringe</li> </ul>	<ul style="list-style-type: none"> <li>a) University Malaya Medical Centre</li> <li>b) Faculty of Medicine, UiTM Sungai Buloh</li> </ul>	LULUS
11.	NN9931-4553	Fasa III	<ul style="list-style-type: none"> <li>a) Semaglutide D 0.5 mg/mL, solution for injection, 0.5mL pen-injector</li> <li>b) Semaglutide D 1.0 mg/mL, solution for injection, 0.5mL pen-injector</li> <li>c) Semaglutide D 2.0 mg/mL, solution for injection, 0.5mL pen-injector</li> </ul>	<ul style="list-style-type: none"> <li>a) University Malaya Medical Centre</li> <li>b) Hospital Selayang</li> <li>c) Hospital Universiti Sains Malaysia</li> </ul>	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			<ul style="list-style-type: none"> <li>d) Semaglutide placebo Ia, solution for injection, 0.5mL pen-injector</li> <li>e) Semaglutide D 2.27 mg/mL, solution for injection, 0.75mL pen-injector</li> <li>f) Semaglutide D 3.2 mg/mL, solution for injection, 0.75mL pen-injector</li> <li>g) Semaglutide placebo Ib, solution for injection, 0.75mL pen-injector</li> </ul>		
12.	D3614C00001	Fasa III	<ul style="list-style-type: none"> <li>a) Tablet Capivasertib (AZD5363) 200 mg</li> <li>b) Tablet Capivasertib (AZD5363) 160 mg</li> <li>c) Placebo for Capivasertib (AZD5363) 200 mg</li> <li>d) Placebo for Capivasertib (AZD5363) 160 mg</li> <li>e) Paclitaxel concentrate for solution for infusion 6 mg/mL (100mg/vial)</li> </ul>	<ul style="list-style-type: none"> <li>a) Hospital Kuala Lumpur</li> <li>b) National Cancer Institute</li> <li>c) Pantai Hospital Kuala Lumpur</li> <li>d) Hospital Umum Sarawak</li> <li>e) University Malaya Medical Centre</li> </ul>	LULUS