

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

<b>Bil.</b>	<b>No. Protokol</b>	<b>Fasa Kajian Klinikal</b>	<b>Nama Produk</b>	<b>Pusat Kajian Klinikal</b>	<b>Status Permohonan</b>
1.	039-19	Kajian BE	Pregabalin Capsule 150mg	<b>Clinical site &amp; Bioanalytical site::</b> RA Chem Pharma Limited Clinical Research & Biosciences Division Plot-No. 26 & 27, Technocrat Industrial Estate (TIE) Balanagar, Hyderabad-500037, India.	LULUS
2.	21-VIN-0135	Kajian BE	Sitagliptin and Metformin Hydrochloride Tablets 50 mg/1000 mg	<b>Clinical site:</b> Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi Ahmedabad, 380015, India.  <b>Bioanalytical site:</b> Veeda Clinical Research Pvt. Ltd. Rev. Sur. No. 12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S. G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India.	LULUS
3.	21-VIN-0136	Kajian BE	Sitagliptin and Metformin Hydrochloride Tablets 50 mg/500 mg	<b>Clinical site:</b> Veeda Clinical Research Pvt. Ltd. Shivalik Plaza-A, Near I.I.M., Ambawadi Ahmedabad, 380015, India.  <b>Bioanalytical site:</b> Veeda Clinical Research Pvt. Ltd.	LULUS

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				Rev. Sur. No. 12/1, Insignia, Corporate House, Nr. Grand Bhagvati Hotel, Sindhu Bhavan Road, S. G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India.	
4.	IK2284-(01) Buprenorphine&Naloxone	Kajian BE	a) Buprenorphine/Naloxone SL Film System A 8mg/2mg (T1) b) Buprenorphine/Naloxone SL Film System B 8mg/2mg (T2)	Sarawak General Hospital	LULUS
5.	MK 6482-012	Fasa II	a) MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial b) Lenvatinib 4 mg Capsule c) Lenvatinib 10 mg Capsule d) MK-1308A, Solution for Infusion, 25mg/400mg (MK-1308 25 mg/MK-3475 400mg), 17.5mL Vial e) Belzutifan (MK-6482) 40mg Tablet	a) Universiti Malaya Medical Centre b) National Cancer Institute/Institut Kanser Negara c) Hospital Kuala Lumpur d) Hospital Sultan Ismail	LULUS
6.	D4325C00001	Fasa II	a) Dapagliflozin film-coated tablet 10 mg b) Zibotentan hard gelatin capsule 5 mg c) Zibotentan hard gelatin capsule 1.5 mg d) Zibotentan hard gelatin capsule 0.25 mg e) Matching placebo for Dapagliflozin film-coated tablet 10 mg f) Matching placebo for Zibotentan hard gelatin capsule 5 mg	a) Hospital Tengku Ampuan Afzan b) Hospital Kuala Lumpur c) Hospital Raja Permaisuri Bainun d) Hospital Sultan Abdul Halim e) Hospital Pakar Sultanah Fatimah f) University Malaya Medical Centre	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			g) Matching placebo for Zibotentan hard gelatin capsule 1.5 mg h) Matching placebo for Zibotentan hard gelatin capsule 0.25 mg		
7.	2017-001-COPAF	Fasa III	a) Colchicine 0.5mg capsules b) Matching placebo Colchicine 0.5mg capsules	a) University Malaya Medical Centre b) Hospital Kuala Lumpur c) Serdang Hospital	LULUS
8.	NW-3509-014-II-2019	Fasa II	a) Evenamide 7.5 mg Capsule b) Evenamide 15 mg Capsule c) Evenamide 30 mg Capsule	a) Hospital Bahagia Ulu Kinta b) Hospital Permai c) University Malaya Medical Centre	LULUS
9.	NW-3509-015-II-2019	Fasa II	a) Evenamide 7.5 mg Capsule b) Evenamide 15 mg Capsule c) Evenamide 30 mg Capsule	d) Hospital Bahagia Ulu Kinta e) Hospital Permai f) University Malaya Medical Centre	LULUS
10.	CMIJ821A12201	Fasa II	MIJ821 20mg Lyophilisate in vial, powder for solution for infusion	a) University Malaya Medical Centre b) Hospital Tuanku Ja'afar c) Hospital Kuala Lumpur	LULUS
11.	D8532C00001	Fasa III	a) AZD9833 film-coated tablet 25mg b) AZD9833-Placebo film-coated tablet 25mg c) AZD9833 film-coated tablet 75mg d) AZD9833-Placebo film-coated tablet 75mg e) Anastrozole film-coated tablet 1mg (Arimidex) f) Anastrozole-Placebo film-coated tablet 1mg	a) University Malaya Medical Centre b) Hospital Pulau Pinang c) Pantai Hospital Kuala Lumpur d) Hospital Sultan Ismail e) Institut Kanser Negara f) Hospital Umum Sarawak g) Hospital Kuala Lumpur	LULUS

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
			<ul style="list-style-type: none"> <li>g) IBRANCE hard capsules 75mg (Palbociclib)</li> <li>h) IBRANCE hard capsules 100mg (Palbociclib)</li> <li>i) IBRANCE hard capsules 125mg (Palbociclib)</li> </ul>		
12.	ALXN2040-PNH-301	Fasa III	<ul style="list-style-type: none"> <li>a) Danicopan (ALXN2040) Film Coated Tablets 50mg</li> <li>b) Danicopan (ALXN2040) Film Coated Tablets 100mg</li> <li>c) Matching Placebo for Danicopan 50 mg Tablet</li> <li>d) Matching Placebo for Danicopan 100 mg Tablet</li> <li>e) Ultomiris (ravulizumab) 300mg/30mL (10mg/mL)</li> </ul>	<ul style="list-style-type: none"> <li>a) Hospital Umum Sarawak</li> <li>b) Hospital Miri</li> <li>c) Hospital Ampang</li> <li>d) Hospital Queen Elizabeth</li> </ul>	LULUS
13.	MK-7684A-002	Fasa II	<ul style="list-style-type: none"> <li>a) MK-7684A 10/10 mg/mL, Solution for Infusion, 20mL vial</li> <li>b) Docetaxel 20 mg/ml, Solution for IV infusion, 80mg vial</li> </ul>	<ul style="list-style-type: none"> <li>a) Hospital Tengku Ampuan Afzan</li> <li>b) Hospital Sultan Ismail</li> <li>c) Beacon Hospital Sdn Bhd</li> <li>d) University Malaya Medical Centre</li> </ul>	LULUS
14.	MK-7684A-003	Fasa III	<ul style="list-style-type: none"> <li>a) MK-7684A 10/10 mg/mL, Solution for Infusion, 20mL vial</li> <li>b) MK-3475 (Pembrolizumab) 25mg/mL, Concentrate for Solution for Infusion, 4mL Vial</li> </ul>	<ul style="list-style-type: none"> <li>a) Hospital Pulau Pinang</li> <li>b) Hospital Tengku Ampuan Afzan</li> <li>c) Gleneagles Penang Medical Center</li> <li>d) National Cancer Institute</li> <li>e) University Malaya Medical Centre</li> </ul>	LULUS