

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN SEPTEMBER 2022

Bil.	No. Protokol	Fasa Kajian Klinik	Nama Produk	Pusat Kajian Klinik	Status Permohonan
1.	0182-22	Kajian BE	Imatinib Tablets 400 mg	Clinical and Bioanalytical site: Lambda Therapeutic Research Ltd Lambda House, Plot No. 38, Survey No. 388, Near Silver Oak Club, S. G. Highway, Gota, Ahmedabad – 382481, Gujarat, India	LULUS
2.	CBCC/2022/003	Kajian BE	Capecitabine Tablets USP, 500mg	Clinical Site: a) KLES Dr. Prabhakar Kore Hospital and Medical Research Centre Belgaum Nehru Nagar, Belagavi, Karnataka-590010, India b) Sanjeevani CBCC USA Cancer Centre, In front of Jain Mandir, Dawada Colony, Pachpedi Naka, Raipur, Chhattisgarh -492001, India c) CIMETs Inamdar Multispeciality Hospital Building S. No. 15, Behind KPCT Mall, Fatima Nagar, Pune-411040, Maharashtra, India d) HCG Manavata Cancer Centre Behind Shivang Auto, Mumbai Naka, Nashik-422002, Maharashtra, India	LULUS

				<p>e) Erode Cancer Centre, SSH 1/393, Velavan Nagar, Perundurai Road, Thindal, Erode-638012, Tamil Nadu, India</p> <p>f) Kiran Multi Super Specialty Hospital Near Sumul Dairy, Katargam, Surat, Gujarat 395004, India</p> <p>g) Sunshine Global Hospital Dumas Road, Beside Big Bazar, Piplod, Surat, Gujarat 395007, India</p> <p>h) Thanjavur Cancer Centre 165/16, By- pass Road, Madhakkottai, Thulukkampatti, Thanjavur-613005, Tamilnadu, India</p> <p>Bioanalytical Site: Veeda Clinical Research Pvt. Ltd. Rev. Sur. No. 12/1, Insignia, Opposite AUDA Garden, Sindhu Bhavan Road, S.G. Highway, Bodakdev, Ahmedabad, Gujarat, 380054, India</p>	
3.	CBR-BD-22-003	Fasa IV	Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 150 million cells in 15 ml of Cryobag)	Hospital Canselor Tuanku Muhriz	LULUS

			Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 200 million cells in 15 ml of Cryobag)		
4.	CBR-PAD-22-004	Fasa IV	Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 150 million cells in 15 ml of Cryobag)	Hospital Canselor Tuanku Muhriz	LULUS
			Stempeucel® (Bone marrow derived ex vivo cultured adult allogeneic Mesenchymal Stromal Cells 200 million cells in 15 ml of Cryobag)		
5.	ARL/22/137	Kajian BE	Erlotinib Tablets 150 mg	Clinical site: Accutest Research Laboratories (I) Pvt. Ltd., 101 to 113 & 201 to 204, 1st and 2nd Floor, Synergy Square Complex, Krishna Industrial Estate, B.I.D.C., Gorwa, Vadodara – 390016, Gujarat, India.	LULUS
			Erlotinib Tablets 150 mg		

6.	CJDQ443B12301	Fasa III	JDQ443 100mg Tablet	<ul style="list-style-type: none"> a) Beacon Hospital b) Sarawak General Hospital c) Sunway Medical Centre d) Pantai Hospital Kuala Lumpur e) University Malaya Medical Centre 	LULUS
7.	MR43808	Fasa III/IV	Faricimab 6mg/0.05mL Vial	<ul style="list-style-type: none"> a) Hospital Shah Alam b) Hospital Selayang 	LULUS
8.	NN8640-4467	Fasa III	Somapacitan 5 mg/1.5 mL Solution for Injection	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Universiti Sains Malaysia (HUSM) c) Hospital UiTM 	LULUS
			Somapacitan 10 mg/1.5 mL; Solution for Injection		
			Somapacitan 15 mg/1.5 mL; Solution for Injection		
			Norditropin® 10 mg/1.5 mL; Solution for Injection		
9.	CNTO1959CRD3 004	Fasa III	Guselkumab 100 mg/1 ml Solution for Infusion or Injection	<ul style="list-style-type: none"> a) University Malaya Medical Centre b) Hospital Tengku Ampuan Afzan c) Hospital Raja Permaisuri Bainun d) Hospital Sultanah Aminah e) Hospital Universiti Sains Malaysia 	LULUS

			Guselkumab 200 mg/2 ml in Prefilled Syringe with YpsoMate Autoinjector (PFS-Y)		
			Placebo for Guselkumab 100 mg/1 ml Solution		
			Placebo for Guselkumab 200 mg/2 ml in Prefilled Syringe with YpsoMate Autoinjector (PFS-Y)		
10.	1366-0031	Fasa II	BI 685509 1mg Film-coated Tablet	a) University Malaya Medical Centre b) Hospital Selayang	LULUS
			BI 685509 2mg Film-coated Tablet		
			BI 685509 3mg Film-coated Tablet		
			BI 685509 Matching Placebo for 1mg Film-coated Tablet		
			BI 685509 Matching Placebo for 2mg Film-coated Tablet		
			BI 685509 Matching Placebo for 3mg Film-coated Tablet		