

STATUS KELULUSAN PERMOHONAN CTIL & CTX PADA BULAN OKTOBER 2023

Bil.	No. Protokol	Fasa Kajian Klinikal	Nama Produk	Pusat Kajian Klinikal	Status Permohonan
1.	BCX10013-105	Fasa Ib	BCX10013, 50 mg capsules	Hospital Ampang	LULUS BERSYARAT
			BCX10013, 80 mg capsules		
			Meningococcal Group B Vaccine Trumenba®, 0.5mL Prefilled Syringe		
			PNEUMOVAX® 23 Pneumococcal Vaccine Polyvalent solution, 0.5 mL single-dose vial		
			HIBERIX [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate) solution for injection, 0.5mL single-dose vial for intramuscular injection		
			PREVNAR 20 (Pneumococcal 20-valent Conjugate Vaccine), 0.5mL pre-filled syringe, suspension for intramuscular injection		
			MenQuadfi®, Meningococcal (Groups A, C, Y, W) Conjugate Vaccine, 0.5mL solution in a single-dose vial for intramuscular injection		
2.	R1979-HM-2299 R1979-ONC-2105 R1979-ONC-22102	Fasa III	1mL of 2mg/mL of Odronextamab (REGN1979) liquid solution in 2mL vial	(a) Hospital Tengku Ampuan Afzan (b) Hospital Queen Elizabeth (c) Hospital Ampang (d) University Malaya Medical Centre (e) Subang Jaya Medical Center (f) Hospital Sultanah Aminah	LULUS
			8mL of 20mg/mL of Odronextamab (REGN1979) liquid solution in 10mL vial		
3.	RLY5016-208p	Fasa II	Patiromer 1 g, Powder for Oral Suspension	(a) University Malaya Medical Centre (b) Hospital Umum Sarawak (c) Sunway Medical Centre (d) Hospital Tunku Azizah	LULUS
			Patiromer Sorbitex Calcium 2 g		
4.	KZR-616-202	Fasa IIb	Single dose 60 mg/vial of Zetomipzomib (KZR-616) powder for solution for injection	(a) Hospital Tengku Ampuan Afzan (b) Hospital Sultan Idris Shah Serdang (c) Hospital Selayang (d) Hospital Raja Permaisuri Bainun (e) Prince Court Medical Centre (f) Hospital Canselor Tuanku Muhriz UKM (g) Universiti Malaya Medical Centre (h) Hospital Al Sultan Abdullah	LULUS
			Single dose 60 mg/vial of placebo for Zetomipzomib (KZR-616) powder for solution for injection		
			Mycophenolate mofetil 500mg film-coated tablets		

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5.	77242113UCO2001	Fasa IIb	JNJ-77242113 100 mg Film-coated Tablet	(a) University Malaya Medical Centre (b) Hospital Sultanah Aminah (c) Sultan Idris Shah Hospital	LULUS
			JNJ-77242113 200 mg Film-coated Tablet		
			JNJ-77242113 Placebo 100 mg Film-coated Tablet		
			JNJ-77242113 Placebo 200 mg Film-coated Tablet		
6.	22-VIN-0211	BE	Vildagliptin 50 mg Tablet	Clinical & Bioanalytical site: Veeda Clinical Research Ltd.	LULUS