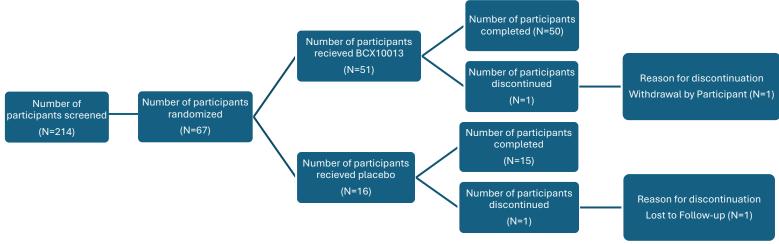
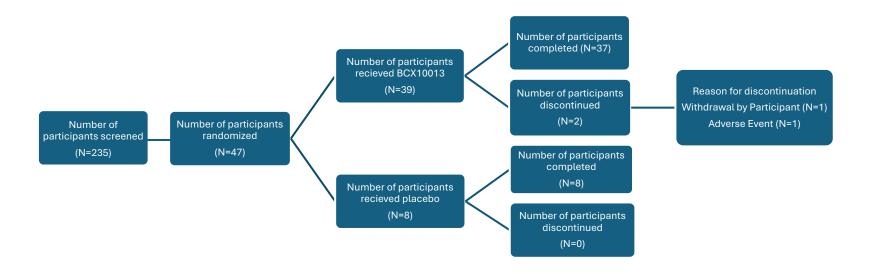
# **Participant flow:**

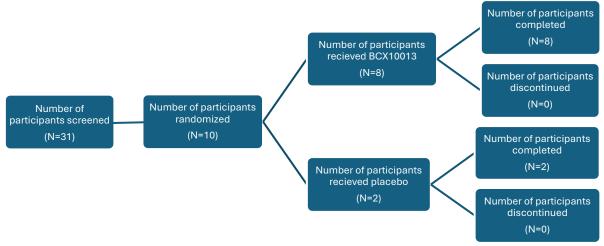
### Part 1: Single Ascending Dose and Pilot Food Effect



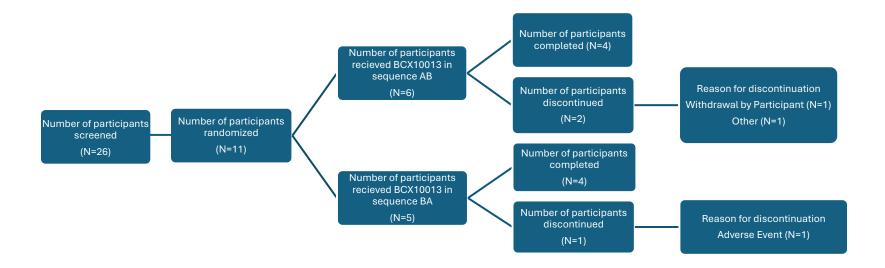
Part 2: Multiple Ascending Dose



### Part 3: Japanese Ethnobridging



Part 4: Relative Bioavailability



# **Baseline Characteristics**

Analysis was performed using safety population.

The safety population included all randomized participants who received at least 1 dose of study drug (BCX10013 or placebo).

		Part 1		Part 2		Part 3		Part 4		
		BCX10013 (N=51)	Placebo (N=16)	BCX10013 (N=39)	Placebo (N=8)	BCX10013 (N=8)	Placebo (N=2)	BCX10013 Sequence AB (N=6)	BCX10013 Sequence BA (N=5)	
Age (years)	Mean (SD)	36.6 (11.97)	35.5 (12.70)	35.9 (11.07)	40.3 (12.74)	38.5 (10.86)	48.0 (11.31)	32.7 (10.50)	39.8 (11.61)	
Sex										
Male	n (%)	25 ( 49.0)	10 ( 62.5)	30 (76.9)	4 ( 50.0)	3 ( 37.5)	2 (100)	3 (50.0)	1 (20.0)	
Female	n (%)	26 ( 51.0)	6 ( 37.5)	9 (23.1)	4 ( 50.0)	5 ( 62.5)	0	3 (50.0))	4 (80.0)	
Ethnicity			, ,		, , , , , , , , , , , , , , , , , , , ,					
Hispanic/Latino	n (%)	2 ( 3.9)	0	1 ( 2.6)	0	0	0	0	0	
Not Hispanic/Latino	n (%)	49 ( 96.1)	16 (100)	38 ( 97.4)	8 (100)	8 (100)	2 (100)	6 (100)	5 (100)	
Race				•			•			
American Indian/Alaska Native	n (%)	0	0	1 ( 2.6)	0	0	0	0	0	
Asian	n (%)	4 (7.8)	3 ( 18.8)	4 ( 10.3)	1 ( 12.5)	0	0	1 ( 16.7)	0	
Black/African American	n (%)	1 ( 2.0)	1 ( 6.3)	0	0	0	0	0	0	
Native Hawaiian/Other Pacific Islander	n (%)	0	0	0	0	0	0	0	0	
White	n (%)	44 ( 86.3)	12 ( 75.0)	33 ( 84.6)	7 ( 87.5)	0	0	5 ( 83.3)	5 (100)	
Other	n (%)	2 ( 3.9)	0	1 ( 2.6)	0	8 (100)	2 (100)	0	0	

N=Total number of participants; n=number of participants; %=percentage

#### **Primary Outcome measure**:

The number of participants with treatment-emergent adverse events (TEAEs) measured using case reports from day 1 up to day 18 (Part 1 and 4) and from day 1 up to day 45 (Part 2)

Analysis was performed using safety population.

Γ				Part 1		ı	Part 2	Part 4		
		BCX10013 (Fasted)	BCX10013 (Fed)	Placebo (Fasted)	Placebo (Fed)	BCX10013 (N=39)	Placebo (N=8)	Dihydrochloride Base	Free Base (N-9)	
		(N=51)	(N=5)	(N=16)	(N=1)			(N=11)		
Ī	n	15	3	7	1	23	5	7	3	

#### **Adverse Events:**

Analysis was performed using safety population.

There were no serious adverse events and no deaths in any part of the study.

	Part 1			Part 2		Part 3	Part 4			
	BCX10013 (Fasted) (N=51)	BCX10013 (Fed) (N=5)	Placebo (Fasted) (N=16)	Placebo (Fed) (N=1)	BCX10013 (N=39)	Placebo (N=8)	BCX10013 (N=8)	Placebo (N=2)	Dihydrochloride Base (N=11)	Free Base (N-9)
n	15	3	7	1	23	5	1	0	7	3
Nervous system disorders	5	1	4	1	8	1	0	0	2	1
Headache	4	1	4	1	6	1	0	0	2	1
Dizziness	1	0	0	0	3	0	0	0	0	0
Hyperaesthesia	0	0	0	0	1	0	0	0	0	0
Paraesthesia	0	0	0	0	0	1	0	0	0	0
Presyncope	0	0	0	0	1	0	0	0	0	0
Gastrointestinal disorders	4	0	2	0	6	1	0	0	4	1
Abdominal discomfort	0	0	1	0	2	0	0	0	0	0
Abdominal pain	1	0	0	0	1	0	0	0	1	0
Abdominal pain upper	0	0	1	0	0	0	0	0	0	0
Cheilitis	1	0	0	0	0	0	0	0	0	0
Diarrhoea	1	0	0	0	0	0	0	0	0	0
Nausea	1	0	0	0	1	0	0	0	1	1
Constipation	0	0	0	0	2	0	0	0	0	0
Abdominal distention	0	0	0	0	1	0	0	0	0	0
Toothache	0	0	0	0	0	1	0	0	0	0

Vomitting	0	0	0	0	0	0	0	0	2	0
Gastroenteritis	0	0	0	0	0	0	0	0	1	0
Infections and	5	0	1	0	6	2	0	0	3	1
infestations		_	-				,	-	_	·
Acarodermatitis	1	0	0	0	0	0	0	0	0	0
COVID-19	0	0	1	0	1	0	0	0	1	0
Folliculitis	1	0	0	0	0	0	0	0	0	0
Influenza	1	0	0	0	0	0	0	0	0	0
Nasopharyngitis	1	0	0	0	1	0	0	0	0	0
Viral upper respiratory tract infection	1	0	0	0	1	1	0	0	1	0
Oral herpes	0	0	0	0	0	1	0	0	1	1
Rhinitis	0	0	0	0	1	0	0	0	0	0
Upper respiratory tract infection	0	0	0	0	1	0	0	0	0	0
Viral rhinitis	0	0	0	0	1	0	0	0	0	0
Musculoskeletal and connective tissue disorders	4	0	1	0	2	0	0	0	0	1
Back pain	4	0	0	0	0	0	0	0	0	1
Arthralgia	0	0	1	0	0	0	0	0	0	0
Groin pain	0	0	0	0	1	0	0	0	0	0
Neck pain	0	0	0	0	1	0	0	0	0	0
General disorders and administration site conditions	3	0	1	0	5	1	0	0	0	0
Medical device site reaction	2	0	1	0	0	0	0	0	0	0
Vessel puncture site swelling	1	0	0	0	0	0	0	0	0	0
Vaccination site pain	0	0	0	0	1	1	0	0	0	0
Chest pain	0	0	0	0	1	0	0	0	0	0
Fatigue	0	0	0	0	1	0	0	0	0	0
Influenza like illness	0	0	0	0	1	0	0	0	0	0
Injection site haematoma	0	0	0	0	1	0	0	0	0	0
Reproductive system and breast disorders	0	1	1	0	2	0	0	0	0	0
Dysmenorrhoea	0	1	1	0	2	0	0	0	0	0
Respiratory, thoracic and mediastinal disorders	0	2	0	0	0	0	0	0	0	0
Cough	0	2	0	0	0	0	0	0	0	0
Blood and lymphatic system disorders	1	0	0	0	0	0	0	0	0	0
Lymph node pain	1	0	0	0	0	0	0	0	0	0
Eye disorders	1	0	0	0	0	0	0	0	0	0
Blepharitis	1	0	0	0	0	0	0	0	0	0
Psychiatric disorders	1	0	0	0	0	0	0	0	0	0
Panic attack	1	0	0	0	0	0	0	0	0	0
Injury, poisoning and	0	0	0	0	4	0	0	0	0	0

Procedural complication										
Vaccination complication	0	0	0	0	2	0	0	0	0	0
Accident	0	0	0	0	1	0	0	0	0	0
Head injury	0	0	0	0	1	0	0	0	0	0
Skin abrasion	0	0	0	0	1	0	0	0	0	0
Thermal burn	0	0	0	0	0	0	1	0	0	0
Ear and labyrinth disorders	0	0	0	0	2	1	0	0	0	0
Deafness	0	0	0	0	1	0	0	0	0	0
Ear pain	0	0	0	0	1	0	0	0	0	0
External ear inflammation	0	0	0	0	0	1	0	0	0	0
Immune system disorders	0	0	0	0	2	0	0	0	0	0
Seasonal Allergy	0	0	0	0	2	0	0	0	0	0
Vascular disorders	0	0	0	0	1	1	0	0	0	0
Haematoma	0	0	0	0	1	1	0	0	0	0
Cardiac disorders	0	0	0	0	1	0	0	0	0	0
Atrial fibrillation	0	0	0	0	1	0	0	0	0	0
Eye Disorders	0	0	0	0	1	0	0	0	0	0
Dry Eye	0	0	0	0	1	0	0	0	0	0