Bio Pharma Services Study Design

[Moxidectin] [FDA] BE

Revision tracker

Prepare by	Date	Revision Comments
JAK	Jan, 2022	New design

Regulatory Body	**FDA**	
Study Drug Information	**Test Product**	**Reference Product**
Strength	2 mg Moxidectin tablets	2 mg Moxidectin tablets
Formulation	Tablets	Tablets
Manufacturer	-	Medicines Development for Global Health
Route	Oral	Oral
Therapeutic Indication	Therapeutic Class: Anthelmintic drug Therapeutic Indication: treatment of onchocerciasis due to Onchocerca volvulus in patients aged 12 years and older.	
Study Profile		
Study Phase	Bioequivalence	
Design	Parallel	
Study Population	Males and non-pregnant, non-lactating females, general population, 18+ years old.	
Smoker Use	Light smokers permitted	
BMI	18.5-30.0 kg/m^2	
Hormonal Contraceptive	Allowed	
Sample Size (# of Subjects)	Pilot (FA): total of 24 subjects (12 subjects in each arm) Pivotal (FA + FE): total of 48 subjects (22 subjects in each arm)	
Study Condition	Fasting + Fed	
In house confinement	-10 to 48 hours post dose	
Washout	N/A *Due to long T1/2 (~33 days), extended lockout might be required. Please contact PK to discuss whether extending the lockdown more than 30 days is required.	
Dosing Schedule	Single dose (1 x 2 mg)	
PK sampling time points	Fa/ Fe: 0, 1, 1.5, 2, 2.5, 2.75, 3, 3.25, 3.5, 3.75, 4, 4.33, 4.67, 5, 5.5, 6, 8, 12, 24, 36, 48, 72 hours post-dose.	
Clinical Safety Monitoring	**Vital Signs (HR + BP)**: 0, 2, 4, 8-, 12-, 24-, 36-, and 72-hours post-dose. **Subjects must remain in a recumbent position for the first 4 hours after dosing.** **Doctor on site: 6 hrs** *Confirmed by [redacted] on Jan 11, 2022.	
Hours of PI monitoring	6 hrs	
Analytical Details		
Analyte(s)	Moxidectin	
Analytical Method	LC-MS/MS	
Matrix	Plasma	
Estimated Analytical Range	**0.2 – 50 ng/ml**	