A Phase 1 Study of the Safety and Tolerability of Single and Multiple Ascending Doses of BWC0977 in Healthy Volunteers

NCT07029932

Status	RECRUITING
Phase	Phase 1
Sponsor	Bugworks Research Inc.
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (20)

- Age: Healthy male or female 18 to 55 years of age, inclusive, at time of consent
- Body mass index (BMI): BMI e 19.0 and d 30.0 (kg/m2) and weight between 55.0 and 100.0 kg (inclusive)
- Health Status: Medically healthy without significant history of any chronic diseases or conditions (such as cardiovascular, renal, hepatic, neurological, hematological, gastrointestinal, endocrine, or musculoskeletal disorders). Volunteers must have no clinically significant abnormalities in medical history, as determined by the Investigator.
- Screening Tests:
- No findings in Physical examination or vital signs (including temperature, heart rate, respiratory rate, and blood pressure) that the Investigator determines would interfere with interpretation of study results

... and 15 more (see full listing online)

Exclusion (16)

- \) Pregnancy and Lactation: Women who are pregnant and/or lactating. 2) Significant Medical History: History or presence of significant cardiovascular (including QT prolongation, clinically significant hypokalemia, or other proarrhythmic conditions), pulmonary, hepatic, renal, hematological, gastrointestinal, endocrine (including glucose intolerance, diabetes mellitus), immunologic (including asthma or seasonal allergies \[that require intermittent use of steroids or other medication\]), musculoskeletal (including tendinopathy), dermatologic, or neurological disease (including seizure disorders, psychiatric disorders), including any acute illness or surgery within the past 3 months, as determined by the Investigator to be clinically relevant.
- History of any kidney disease or current or chronic history of impaired renal function as indicated by a calculated creatinine clearance (Cockcroft-Gault formula) \<80 milliliter per minute (mL/min).
- Current or chronic history of liver disease or known hepatic or biliary abnormalities (except for Gilbert syndrome or asymptomatic gallstones) 3) Laboratory abnormalities
- a) Clinically significant abnormal findings in serum chemistry, hematology, coagulation or urinalysis results obtained at screening or check-in (Day-1) b) Alanine aminotransferase (ALT) more than (\>)1 upper limit of normal (ULN) at screening or check-in (Day-1) c) Aspartate aminotransferase (AST) \> ULN at screening or check-in (Day-1)d) Bilirubin \>ULN at screening or check-in (Day-1) e) Serum creatinine \> ULN at screening or check-in (Day-1). The serum creatinine or any laboratory test may be repeated prior to confirming exclusion, at the PI's discretion.
- \) Electrocardiographic abnormalities: Baseline QTcF of \>450 msec (for males), and \>470 msec (for females) at screening or check-in (Day-1) 5) Photosensitivity: History of photosensitivity to quinolones 6) Clostridium Difficile: History of known or suspected Clostridium difficile infection 7) Hospitalization History: Any condition that necessitated hospitalization within the 3 months prior to Day -1 or is likely to require so during the study 8) Antibiotic History: No systemic antibiotic use within 5 days before dosing. 9) Infection History: Positive test for hepatitis B virus surface antigen (HBsAg), hepatitis C virus antibody (anti-HCV antibodies), or human immunodeficiency virus antibody (antibodies to HIV-1, HIV-2) at screening.

... and 11 more (see full listing online)

Locations (1 total)

Nucleus Network, Melbourne, Victoria, Australia