A First-in-Human Study to Evaluate Safety, Tolerability, and Pharmacokinetics of Single and Multiple Oral Doses of Debio 1453P in Healthy Adults

NCT07035769

Status	RECRUITING
Phase	Phase 1
Sponsor	Debiopharm International SA
Enrollment	88 participants

Key Eligibility Criteria

Inclusion (3)

- Signed and dated written informed consent obtained before undertaking any trial-specific procedures.
- Be within the age range of 18 to 55 years, inclusive, at the time of screening.
- Have a body mass index (BMI) e18.5 and d30.0 kg/m\^2.

Exclusion (3)

- History and/or physical examination evidence of any clinically significant disease or disorder, such as cardiovascular, pulmonary, renal, hepatic, neurological, gastrointestinal, endocrine, immunological, psychiatric or mental disease or disorder, or mental or legal incapacitation, which, in the opinion of the Investigator, may either put the participant at risk for taking part in the trial, influence the results of the trial, influence the participant's ability to take part in the trial.
- Any medication (including vaccines, over the counter (OTC) and/or prescription medication, dietary supplements, nutraceuticals, vitamins and/or herbal supplements, and hormonal replacement therapy for postmenopausal participants) for 2 weeks or 5 half-lives of the drug, whichever is longer, prior to first administration of trial drug (except occasional paracetamol (maximum dose of 2 g/day and maximum of 10 g/2 weeks).
- History of chronic drug or alcohol abuse (defined as an average intake of more than 21 units of alcohol per week for males and 14 for females. 1 unit of alcohol equals approximately 250 mL of beer, 100 mL of wine, or 35 mL of spirits) in the last 2 years.

Locations (1 total)

SGS Belgium NV - Clinical Pharmacology Unit, Edegem, Belgium

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