A Clinical Trial to Test the Safety, Tolerability, and How the Body Processes CPV-104 in Healthy People and Patients With C3-Glomerulopathy

NCT07483827

Status	RECRUITING
Phase	Phase 1
Sponsor	eleva GmbH
Enrollment	39 participants

Key Eligibility Criteria

Inclusion (10)

- Participants must be at least 18 years old and no more than 50 years old, at the time of consent, and must be able to sign and date the informed consent form (ICF) themselves.
- Patient must be at least 18 years old, at the time of consent, and must be able to sign and date the informed consent form (ICF) themselves.
- Patient must have a diagnosis of C3G confirmed by historical renal biopsy.
- Patient must have proteinuria at screening.
- Patient must have stable or worsening renal disease, be on stable and optimized symptomatic treatment, in the opinion of the PI, for at least 30 days prior to screening (treatments may include, but are not limited to, immunosuppressive agents, anti-hypertensives, steroids).

... and 5 more (see full listing online)

Exclusion (44)

- Body weight within 50 kg for male/ 45 kg for female to 110 kg and BMI within the range 18 - 32 kg/m2 (inclusive).
- Childbearing potential (CBP) participants should agree to use a highly effective method of contraception throughout the study and for 90 days after the last dose of the IMP.
- CBP participants should agree not to donate oocytes or freeze for future use for the purposes of assisted reproduction during the study and for a period of 90 days after the last dose of the IMP. Male participants should agree not to donate sperm or freeze sperm for future use for the purposes of assisted reproduction during the study and for a period of 90 days after the last dose of the IMP.
- CBP participants should have a negative pregnancy test at screening.
- Participant provides written informed consent which includes compliance with the requirements and restrictions listed in the ICF and in this protocol.

... and 39 more (see full listing online)

Locations (16 total)

Medizinische Universität Wien, Vienna, Austria
Cliniques universitaires Saint-Luc, Brussels, Belgium
Fakultni Thomayerova nemocnice, Prague, Czechia
... and 13 more locations