ADAPT Study: Long-term Safety Study of INZ-701 in Patients With ENPP1 Deficiency and ABCC6 Deficiency

NCT06462547

Status	RECRUITING
Phase	Phase 2
Sponsor	Inozyme Pharma
Enrollment	200 participants

Key Eligibility Criteria

Inclusion (7)

- Provide written or electronic informed consent after the nature of the study has been explained, and prior to any research-related procedures, per International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP)
- Provide assent in accordance with local regulations, if \<18 years of age
- Male or female, greater than 1 year of age
- Must have completed the protocol-required safety and PK/PD and/or efficacy period(s) of a previous INZ-701 clinical study in ENPP1 or ABCC6 Deficiency, as confirmed by the Sponsor
- Female participants of childbearing potential who are sexually active must be using or agree to use 1 highly effective form of contraception (per CTFG 2020) from at least 1 month before the first dose of INZ-701 through 30 days after last dose of INZ-701 (greater than 5 half-lives of INZ-701); participants must agree to not donate ova from the period following the first dose of INZ-701 through 30 days after the last dose of INZ-701

... and 2 more (see full listing online)

Exclusion (5)

- In the opinion of the Investigator, presence of any clinically significant disease or laboratory abnormality not associated with ENPP1 Deficiency or ABCC6 Deficiency, that will preclude study participation and/or may confound interpretation of study results
- Known intolerance to INZ-701 or any of its excipients
- Concurrent participation in another interventional clinical study and/or has received an investigational drug other than INZ-701 within 5 half-lives or within 4 weeks prior to the first dose of INZ-701 in this study, whichever is longer, or use of an investigational device
- Pregnant, trying to become pregnant, or breastfeeding
- Male participants trying to father a child

Locations (5 total)

Mayo Clinic, Rochester, Minnesota, United States
Clinilabs Drug Development Corporation, Eatontown, New Jersey, United States
Necker-Enfants Malades Hospital, Paris, France
... and 2 more locations