Study to Evaluate the Safety, Tolerability, Efficacy and Pharmacokinetics of JTE-162 in Subjects With Cryopyrin-Associated Periodic Syndrome (CAPS)

NCT07247266

Status	RECRUITING
Phase	Phase 1
Sponsor	Akros Pharma Inc.
Enrollment	5 participants

Key Eligibility Criteria

Inclusion (5)

- Diagnosed with familial cold autoinflammatory syndrome (FCAS) or Muckle-Wells syndrome (MWS) confirmed by:
- Clinical History: At least 2 typical clinical symptoms (e.g., urticarial skin rash, myalgia, arthralgia, recurrent fever, fatigue/malaise, conjunctivitis or other autoinflammatory symptoms) prior to the Screening Visit; AND
- Genetic Confirmation: Confirmed nucleotide-binding and oligomerization domain (NOD)-like receptor family pyrin domain containing 3 (NLRP3) mutation;
- Willing to discontinue current anti-interleukin (IL)-1 treatment, if applicable;
- Demonstrates de novo flaring of CAPS during the Screening Period.

Exclusion (3)

- Has chronic infantile neurologic cutaneous articular syndrome (CINCA)/neonatal-onset multisystem inflammatory disease (NOMID);
- Has a history or presence of amyloidosis, progressive hearing loss, organ damage or any symptom contraindicating anti-IL-1 treatment washout;
- Has active systemic bacterial, fungal or viral infection(s) within 14 days prior to Day 1 or a history of clinically significant recurrent infectious diseases

Locations (1 total)

Gordon Sussman Clinical Research Inc., North York, Ontario, Canada