CLF065 for Chronic Pouchitis

NCT07226050

Status	RECRUITING
Phase	Phase 2
Sponsor	Calibr, a division of Scripps Research
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (12)

- Adult subjects aged 18-80 years, inclusive.
- In the opinion of the investigator, the subject is capable of understanding and complying with protocol requirements.
- The subject signs and dates a written, informed consent form and any required privacy authorization prior to the initiation of any study procedures.
- Diagnosis of pouchitis that is recurrent, defined by mPDAI score of e 5 assessed as the average from 3 days immediately prior to Baseline endoscopy, and a minimum endoscopic subscore of 2 (outside the staple or suture line) with either:
- e 3episodes of pouchitis within 1 year of Screening visit, each treated with antibiotic or other prescription therapy for at least 2 weeks OR Requiring maintenance antibiotic therapy taken continuously for e 4 weeks immediately prior to the Baseline endoscopic visit

... and 7 more (see full listing online)

Exclusion (27)

- Inability to give informed consent.
- The patient has received any investigational product or approved biologic or biosimilar agent within 60 days of 5 half-lives of randomization (whichever is longer)
- No prior exposure to CLF065
- Chronic pouchitis specific:
- The patient has received 6-MP, Azathioprine or methotrexate within 4 weeks of the Screening Visit

... and 22 more (see full listing online)

Locations (1 total)

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