A Study to Test Whether Spesolimab Helps People With a Skin Condition Called Pyoderma Gangrenosum

NCT06624670

Status	RECRUITING
Phase	Phase 3
Sponsor	Boehringer Ingelheim
Enrollment	90 participants

Key Eligibility Criteria

Inclusion (6)

- Adult trial participants, aged e18 years (if local legislation for age of consent differs, then local legislation will be followed) at screening.
- Signed and dated written informed consent in accordance with International Council on Harmonisation-Good Clinical Practice (ICH-GCP) and local legislation prior to admission to the trial.
- A confirmed diagnosis of ulcerative pyoderma gangrenosum (PG) (e10 points on the PARACELSUS score) that requires systemic therapy in the opinion of the investigator. The diagnosis needs to be confirmed by an Adjudication Committee. Trial participants with mixed PG subtypes are eligible as long as the target lesion is of the ulcerative subtype.
- At least one measurable (defined as measuring e5 cm\^2) PG ulcer. In trial participants with more than one PG ulcer, the target PG ulcer will be selected by the investigator and confirmed by external Adjudication Committee.
- At the time of the Screening Visit, a maximum duration of 6 months since the target ulcer in the current PG episode was diagnosed. Target ulcers \>6 months since diagnosis are allowed if they are active and progressing, as judged by the investigator and confirmed by an Adjudication Committee.

... and 1 more (see full listing online)

Exclusion (10)

- Trial participants with non-PG lesions.
- Trial participants with a target PG ulcer measuring \>80 cm\^2.
- Trial participants with chronic, non-inflamed PG wounds or ulcers that are not responsive to immunosuppressive therapy, as determined by an Adjudication Committee.
- Presence of active ulcer infection at the Screening Visit (unless treated and resolved prior to administration of the first dose of trial medication) based on investigator assessment.
- Presence of persistent or recurring bacterial infection requiring systemic antibiotic therapy; or clinically significant viral, fungal, or parasitic infections within 2 weeks prior to the Screening Visit. Any such infection must be resolved, with treatment completed e2 weeks prior to the Screening Visit. No new/recurrent infections should have occurred prior to Visit 2.

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

Locations (95 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
Medical Dermatology Specialists Phoenix, Phoenix, Arizona, United States
University of California Irvine, Irvine, California, United States
... and 92 more locations