

A phase 3, multicenter, randomized, placebo-controlled, double-blind, parallel-group trial to evaluate the safety and efficacy of spesolimab (BI 655130) in adult patients with ulcerative pyoderma gangrenosum (PG) who require systemic therapy¹

Use of spesolimab in this setting is investigational. Safety and efficacy have not been established.

Unmet needs in PG



PG is a rare, potentially life-threatening disease that begins as sterile small pustules, papules, and blisters that rapidly evolve into painful ulcers^{2,3}; as such, PG is associated with a substantial burden on quality of life⁴



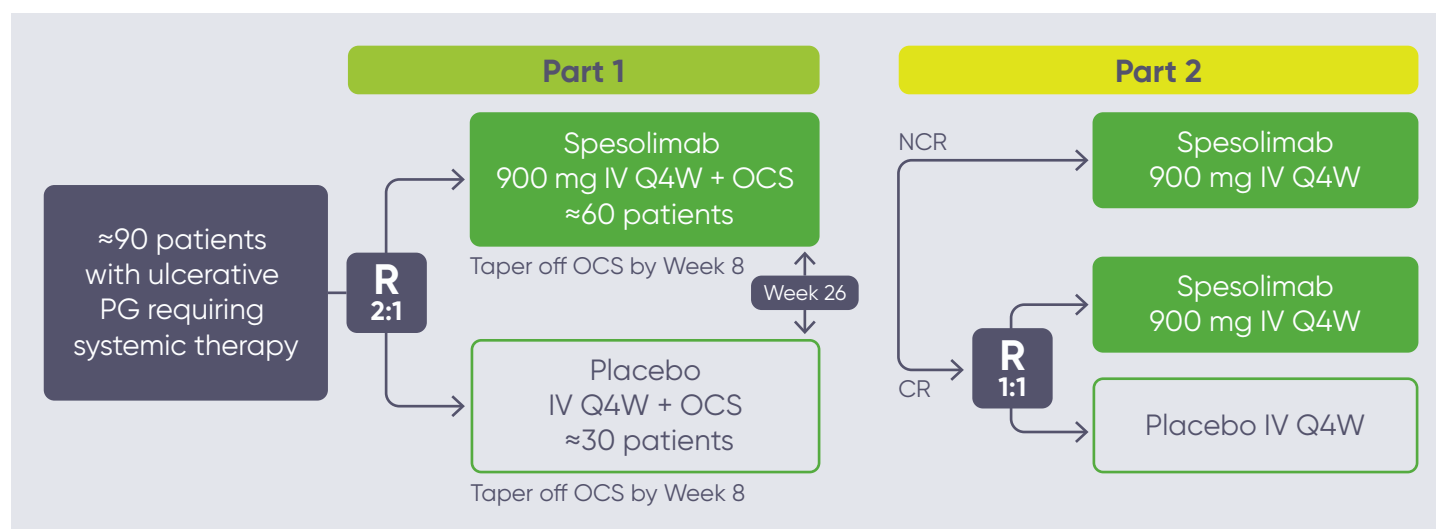
Systemic corticosteroids and cyclosporine are considered first-line treatments but have been observed to only induce wound closure in approximately 50% of patients, with ulcer recurrence observed in approximately 30% of patients^{2,5}



There are no FDA-approved therapies for PG⁶

Study design¹

- Estimated study duration is approximately 1.5 years, with IV dosing every 4 weeks
- In part 1, patients will have a 2-in-3 chance of being randomized to spesolimab
- After Week 26, patients who have an insufficient response will receive spesolimab



Trial objective¹

- Evaluate the safety and efficacy of repeat dosing with spesolimab vs placebo

Primary endpoint¹

- Complete closure of target PG ulcer at any time up to Week 26

Key inclusion/exclusion criteria^{1,a}

Key inclusion criteria

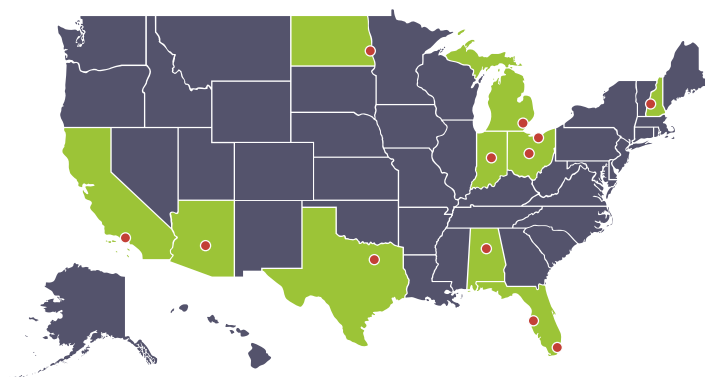
- ≥ 1 measurable PG ulcer (defined as measuring ≥ 5 cm²)
- At the time of the screening visit, a maximum duration of 6 months since the target ulcer in the current PG episode was diagnosed. Target ulcers with >6 months since diagnosis are allowed if they are active and progressing

^a Additional criteria apply

Key exclusion criteria

- Non-PG lesions or a target PG ulcer that is >80 cm²
- Chronic, noninflamed PG wounds or ulcers that are not responsive to immunosuppressive therapy
- Presence of an active ulcer infection; persistent or recurring bacterial infections; clinically significant viral, fungal, or parasitic infections within 2 weeks of screening

Clinical trial locations



Birmingham, AL
Phoenix, AZ
Irvine, CA
Miami, FL
Tampa, FL
Indianapolis, IN
Ann Arbor, MI

Fargo, ND
Lebanon, NH
New Hyde Park, NY
Cleveland, OH
Columbus, OH
Dallas, TX

ClinicalTrials.gov identifier: NCT06624670

For more information:

Phone: 1-800-243-0127 (select option 4)

Email: clintriage.rdg@boehringer-ingelheim.com



Scan QR code to learn more about the CAPSAYIL™ trial.

Patients and caregivers in this trial are supported by patient concierge services through Scout Clinical.

- Participating US patients are eligible for travel and accommodation support throughout the duration of their study participation.

For more information, please contact 1-800-601-0012.



CR, complete response; FDA, US Food and Drug Administration; IV, intravenous; NCR, noncomplete response; OCS, oral corticosteroid; PG, pyoderma gangrenosum; Q4W, every 4 weeks; R, randomized.

1. ClinicalTrials.gov. Accessed June 2025. <https://clinicaltrials.gov/study/NCT06624670>. 2. Maverakis E, et al. *Nat Rev Dis Primers*. 2020;6(1):81.

3. Yamamoto T, et al. *J Dermatol*. 2023;50(9):e253–e275. 4. Ighani A, et al. *Br J Dermatol*. 2019;180(3):672–673. 5. Ormerod AD, et al. *BMJ*. 2015;350:h2958.

6. Rick J, et al. *Arch Dermatol Res*. 2023;315(4):983–988.

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