A Phase 2 Study of TCP-25 Gel in Patients With Epidermolysis Bullosa, STEP-study

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 4 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Male or female patients with documented diagnosis of DEB or JEB, confirmed by genetic testing and/or by a skin biopsy with immunofluorescence mapping.
- Patients ≥4 years old. Note: Initially, patients ≥12 years will be enrolled. Enrollment will be open to 4 to 11 year old pediatric patients (both inclusive), after a DMC reviews and provides a positive opinion regarding the safety and tolerability of the IMP in at least 3 patients 12 to 18 years old who have completed at least 4 weeks of IMP use.

Exclusion Criteria:

- The patient has any subtype of EB other than DEB or JEB.
- The patient is currently being treated or planned to be treated with systemic antibiotics.

Note: Use of preventive and/or anti-inflammatory antibiotic treatment, including doxycycline, on an established treatment regimen (stable dose for ≥6 weeks before the Baseline Visit) is permitted. Use of topical antibiotics on the index wounds within 7 days before the Baseline Visit is prohibited.

• Use of systemic corticosteroids >0.2 mg/kg prednisone dose equivalent per day within 30 days or use of topical corticosteroids on index wounds within 7 days before the Screening Visit.

Note: Corticosteroids for inhalation, ophthalmic, or intranasal use are permitted.

• The patient has a history of or current malignancy over the index wound, eg, basal cell carcinoma or squamous cell carcinoma.

Conditions & Interventions

Interventions:
DRUG: TCP-25 gel, DRUG: Vehicle (placebo)
Conditions:
Epidermolysis Bullosa (EB), Dystrophic Epidermolysis Bullosa, Junctional Epidermolysis Bullosa
Keywords:
epidermolysis bullosa, topical treatment

More Information

Description:
This is a Phase 2, double-blind, randomized, vehicle-controlled study designed to evaluate efficacy, safety, and tolerability of topically applied TCP-25 gel in patients with confirmed DEB or JEB. The study will implement intrasubject randomization, ie, a pair of matching index wounds will be randomly assigned to be treated with a local application of either TCP 25 gel or vehicle gel.

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