A Study Comparing KB803 and Matched Placebo in Patients With Dystrophic Epidermolysis Bullosa

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 6 month(s) and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. The subject and/or their parent/legal guardian must provide informed consent/assent and must be able to and willing to follow study procedures and instructions.
2. Age 6 months or older at time of informed consent/assent.
3. Confirmed diagnosis of DEB with a mutation in the COL7A1 gene.
4. Meets minimum corneal abrasion symptom frequency in the NHS study.

Exclusion Criteria:

1. Initiation of any new treatment regimen or change in treatment for ocular disease during the run-in period except for preservative free topical antibiotics or artificial tears/lubricants associated with standard of care treatment of corneal abrasions.
2. Treatment with an investigational agent or off-label ophthalmic use of an approved product during the run-in period or planned use during the study (Exceptions may be approved by the medical monitor on a case-by-case basis).
3. Any condition that, in the opinion of the Investigator, would impact the completion of all study-related assessments, interfere with the administration of study drug, and/or poses an additional risk to the subject.
4. Women who are pregnant or nursing.
5. Subject who is unwilling to comply with contraception requirements per protocol.
6. Subject is known to be noncompliant or is unlikely to comply with the requirements of the study protocol in the opinion of the Investigator.

Conditions & Interventions

Interventions:
BIOLOGICAL: KB803, DRUG: Placebo
Conditions:
Dystrophic Epidermolysis Bullosa, DEB - Dystrophic Epidermolysis Bullosa, Recessive Dystrophic Epidermolysis Bullosa, Dominant Dystrophic Epidermolysis Bullosa
Keywords:
Dystrophic Epidermolysis Bullosa, DEB, Corneal Abrasions

More Information

Description:
KB803-EYE-01 is a Phase 3 double-blind, randomized, placebo-controlled, crossover study to evaluate the safety and efficacy of KB803 versus matched placebo in pediatric and adult subjects with recurrent corneal abrasions due to dystrophic epidermolysis bullosa (DEB).

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