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IRB Approved at the
Protocol Level
Nov 12, 2018

EASE Study: A clinical trial of an investigational topical therapy for the treatment of wounds related to EB, from Amryt Pharma. Now enrolling, including study sites in the US

Amryt Pharma is currently conducting a global phase III study-Efficacy and Safety Study of Oleogel-S10 in Epidermolysis Bullosa (the EASE study), to investigate whether Oleogel-S10 (AP101) is safe and efficacious for the treatment of EB wounds in patients with Dystrophic and Junctional EB, and Kindler Syndrome.

Oleogel-S10 (AP101), has not been adequately studied and is not approved for the treatment of wounds related to EB. It must be studied further to learn more about its safety and effectiveness in the treatment of wounds in patients with certain types of inherited of Epidermolysis Bullosa (Dystrophic, Junctional, and Kindler Syndrome).

Oleogel-S10 (AP101) was developed by Amryt Pharma, (trade name, Episalvan®) and was approved in the European Union in January 2016 for the treatment of partial thickness wounds in adults. A topical gel, Oleogel-S10 (AP101), contains 90% Sunflower oil and 10% dry birch bark extract with the active ingredients, triterpene extracts, which is predominately betulin (72%-88%).

EASE Trial Summary:

The EASE study protocol requires participating patients to apply Oleogel-S10 or placebo (sunflower oil vehicle gel) to an eligible primary target wound identified by the Study Investigator in addition to all other EB wounds. Patients are allowed to apply the study medication according to their preferred schedule of wound dressing changes ranging from every day to as long as every 4 days. Patients may use their choice of non-adhesive dressing.

After an initial 3 months of treatment with either Oleogel-S10 (AP101) or vehicle (placebo) gel, all patients will receive Oleogel-S10 (AP101) in an open-label, 24-month safety extension. Patients will be asked to comply with the study protocol and complete all scheduled study visits.

Please click on the link for more information on the EASE study at www.clinicaltrials.gov. Up to date information about the EASE study, including study design, study inclusion and exclusion criteria, study site information, including location and how to contact a site directly is available on this FDA website.

Amryt Pharma is reaching out to EB clinical centers interested in being considered as potential clinical trial sites. Potential sites should contact easestudy@amrytpharma.com.

Patients who wish to consider participation in the EASE study or other clinical trials, please speak with your physician.