

Amryt EASE study opens for recruitment at Children's Hospital Colorado, Denver.

Amryt, a company focused on developing products that help to improve the lives of patients where there is a high unmet medical need, today announced that **Anna Bruckner, MD, Children's Hospital Colorado in Denver, CO**; joins **John Browning, MD, Texas Dermatology and Laser Specialist, San Antonio, TX** and is now open to recruit patients with Epidermolysis Bullosa (EB) into the Global EASE study. The EASE study is investigating Oleogel-S10, a topical treatment for the wounds associated with inherited EB.

Up to 10 trial sites are planned in the US and initiation of **Children's Hospital Colorado** is a significant milestone in accelerating patient recruitment into the EASE study. The EASE study has existing trial sites in Europe, Australasia, Latin America and the Middle East. The US Food and Drug Administration ("FDA") granted Investigational New Drug ("IND") clearance for the EASE study in September 2018.

Up to date information about the EASE study, including study design, study site information, and how to contact a site directly is available on clinicaltrials.gov

A recent interim efficacy analysis occurred when 50% of study patients were enrolled into the EASE study. The purpose of this analysis was to check that sufficient patients were enrolled in the study to detect a difference in the efficacy on wound healing of Oleogel-S10 compared with placebo. The recommendation of an independent data monitoring committee (IDMC) was to increase in the number of evaluable subjects in the study from 182 to a total of 230.

An interim safety analysis has also been conducted. The IDMC interim safety analysis has recommended that sites can now enroll infants and children with EB between the ages of 21 days to 4 years of age in to the trial. The IDMC's analysis was conducted using pharmacokinetic ("PK") data received from patients already enrolled in the trial (aged four years and older).

Amryt will begin the recruitment process for infants and children into EASE immediately. The EASE trial is the largest ever global Phase III study conducted in patients with EB.

Amryt is encouraged by the news. The modest increase in patients required for the study and extending the age eligibility criteria is positive news and a significant step forward in addressing the unmet need in this devastating condition, which is present from birth in most cases. Amryt would like to thank sincerely the patients, families and clinical investigators involved in the EASE trial.