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TWi Biotech completes patient enrollment for treatment of Epidermolysis Bullosa

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TWi Biotechnology (TWiB), a clinical stage biopharmaceutical company focused on development of novel products for rare diseases associated with chronic inflammation, announced today that it has completed patient enrollment in its Phase 2 clinical trial (Study code: AC-203-EBS-005) of AC-203 for the treatment of inherited Epidermolysis Bullosa (EB), including Epidermolysis Bullosa Simplex (EBS), Dystrophic Epidermolysis Bullosa (DEB) and Junctional Epidermolysis Bullosa (JEB). The Phase 2 clinical trial is the first multi-center, double-blind, randomized, placebo-control, intra-individual comparison study conducted to evaluate the efficacy, safety and tolerability of AC-203 in different EB sub-types. Launched in October 2018, enrollment was completed within 3 months with 9 subjects randomized at 2 sites in Hsinchu and Tainan. The company expects to report top-line results in second quarter of 2019. The trial results will help support TWIB's global development partner, Castle Creek Pharma (CCP), to extend the indication in both US and EU.

Enrolled patients will complete 8 weeks of once daily topical treatment in two designated lesion areas (one with AC-203 and one with placebo) followed by 4 weeks of follow-up period with no treatment. To evaluate efficacy, the study measures change of lesion surface areas in blisters, erythema, erosion and crust within the designated lesion areas from baseline by treatment. Other assessments include safety, pruritus and pain scale, levels of pro-inflammatory cytokines, and analysis of daily digital skin images of lesions taken by patients.

"EB is a debilitating skin disease without any effective or FDA-approved treatment. Some EB sub-types could be lethal and patients are more at risk for developing squamous cell carcinoma. It is a huge burden for the patients and families. Completing patient enrollment for AC-203-EBS-005 at such a short time is an important milestone for TWiB and triumph for EB patients, and we are grateful for the support of trial participants and their families, patient groups and investigators to achieve our enrollment goal," commented Calvin Chen, Ph.D., Chief Executive Officer of TWiB. "We are committed to bring AC-203 treatment to EB patients and believe the results of this study will be an essential step for future global registration trial in partnership with CCP. In addition, the study will offer a good opportunity to allow our local investigators to integrate into the international EB research community."