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TWi Biotechnology gets TFDA nod to treat Inherited Epidermolysis Bullosa

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TFDA approves phase 2 clinical trial of AC-203 for the treatment of inherited Epidermolysis Bullosa (EB)

TWi Biotechnology,a clinical stage biotechnology company focused on developing inhibitors of inflammasomes.

The company announced that it has received approval from the Taiwan Food and Drug Administration (TFDA) to proceed a phase 2 clinical trial of AC-203 for the treatment of inherited Epidermolysis Bullosa (EB).

This trial is designed to be a double-blind, intra-individual comparison, proof-of-concept clinical trial, and will enroll patients as young as 2 year old.

The primary efficacy endpoint is the reduction of lesion surface in patients with EB. TWi Biotech expects the first patient will be enrolled in early April this year.

The approval of the trial can enroll very young patients, 2 year old, is very important, because the younger the age of patients, the disease symptoms are more severe, and the risks of patient developing chronic complications and even death are higher.

The pivotal trial DELIVERS is approved to test in patient equal or more than 4 years old.

There isn't any approved drug for any type of EB. The wound care of EB patients has to be meticulous and can be very traumatic to patients and caregivers.