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ASIA EDITION

TWiB receives Canada Health Approval for potential vitiligo drug

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AC-1101 is a repurposing product for topical treatment of inflammatory skin diseases including vitiligo

Taiwan based TWi Biotechnology (TWiB) announced that they have received Clinical Trial Application (CTA) approval from Health Canada to conduct a Phase 1 clinical trial with AC-1101 gel. AC-1101 is a topical JAK inhibitor for the potential treatment of patients with vitiligo. Currently, there are no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA)-approved drug therapies for the treatment of vitiligo.

The AC-1101 Phase 1 trial is an open-label, fixed-sequence, two-period, comparative bioavailability study of AC-1101 from repeated topical applications of AC-1101 gel to single oral administration of its oral reference product in healthy adult volunteers in Canada and is expected to be completed at the end of 2020.

AC-1101 is a repurposing product for topical treatment of inflammatory skin diseases including vitiligo. The purpose of this first clinical trial is to bridge the pharmacokinetics and safety of our unique topical product with the marketed oral product. The Phase 1 study results will support to advance AC-1101 to the next Phase 2 dose-ranging clinical trial and regulatory milestones.

AC-1101 gel is a topical formulation of an FDA approved-oral JAK inhibitor. AC-1101 gel is developed to treat a wide variety of inflammatory skin diseases such as atopic dermatitis and vitiligo.