Clinuvel Pharmaceutical Publishes Positive Data on SCENESSE® in Rare Skin Disorder

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Clinuvel Pharmaceuticals Limited:

Physician-led pilot study successful in Hailey-Hailey disease, future Phase II in development
Clinuvel Pharmaceuticals Limited (ASX: CUV; XETRA-DAX: UR9; ADR: CLVLY) today announced that results from a physician-led pilot study of SCENESSE® (afamelanotide 16mg implant) have been published in the journal Clinical and Experimental Dermatology. The pilot study, in two patients with the rare Hailey-Hailey Disease (HHD), indicates for the first time that afamelanotide may be of therapeutic benefit by offering long-term remission (disease free period).

Hailey-Hailey Disease

Hailey-Hailey Disease (HHD, also known as familial benign pemphigus) is a rare, chronic, inherited disorder where epidermal skin cells (keratinocytes) don't adhere correctly. This causes periodic eruption of plaque-like lesions and blisters on areas where skin folds, often on the neck, armpits or groin. HHD can be very distressing for patients, with outbreaks on the legs and groin leading to immobilisation due to the pain of friction, and a high risk of skin infection.

Current treatments, including topical corticosteroids and antibiotics, can manage minor outbreaks, but are seen as ineffective in severe cases, and there is no professional consensus on a first-line therapy as no remission has been achieved in these patients. Exact prevalence of HHD is unknown, however clinical reports to Clinuvel suggest that there are 20-30 HHD affected families in most Western European countries.

Published observations from preclinical and clinical pilot studies

The study authors hypothesised that an antioxidant effect of afamelanotide in keratinocytes may assist in reducing the effect of HHD and published several preclinical observations, based on laboratory work, to support their hypothesis, noting that the "clinical and laboratory results provided a strong rationale for the use of afamelanotide for the treatment of HHD".

A physician-led open-label observational study of SCENESSE® was then conducted in two HHD patients at San Gallicano Hospital in Rome. Both patients received two doses of SCENESSE®, one at the start of the study and the second after 30 days. In both patients lesions were reduced after 30 days and completely resolved after 60, with no disease recurrence until eight months after the withdrawal of treatment. Both patients reported an improvement in quality of life, measured by the SF-36 dermatology questionnaire, a common assessment tool in clinical studies. The drug was well tolerated by both patients.

Comment

"HHD is a poorly understood disease which has a chronic impact on the lives of patients and lacks an effective therapy," Clinuvel's Acting Chief Scientific Officer, Dr Dennis Wright said. "It's encouraging that afamelanotide may be able to benefit HHD patients."

"Clinuvel is well aware of the potential of afamelanotide to treat a number of skin disorders," Clinuvel's CEO, Dr Philippe Wolgen said. "This research proposes a new avenue for afamelanotide to help treat an expanded group of patients with severe, chronic and rare disorders. Based on the clinical observations to date, Clinuvel's team is now working with leading HHD physicians to arrive at a larger study designed to demonstrate a clinically meaningful effect for patients to achieve long term remission; a life without lesions. Perhaps most reassuring from this publication is that SCENESSE® was well tolerated by these patients, consistent with the drug's long standing safety profile."

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