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Devonian receives Health Canada authorisation for paediatric Thykamine trial

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The Phase II/III study will evaluate two concentrations of Thykamine cream in children with mild-to-moderate atopic dermatitis.

DEVONIAN

Devonian Health Group has received Health Canada authorisation to initiate a Phase II/III paediatric clinical trial of PUR 0110, also known as Thykamine, for mild-to-moderate atopic dermatitis.

The trial will evaluate Thykamine cream in paediatric patients aged three months to 17 years. Health Canada authorised the full intended paediatric population, including infants, children and adolescents.

The study is a 12-week multicentre, randomised, double-blind, parallel-group, placebo-controlled trial. It will evaluate two concentrations of Thykamine cream, 0.05 per cent and 0.1 per cent, applied twice daily.

The primary objective is to evaluate efficacy compared with placebo after 12 weeks of treatment. Secondary objectives include assessment of safety and tolerability.

The trial uses a seamless adaptive Phase II/III design, with an interim analysis after completion of Phase II to allow transition into the confirmatory Phase III part of the programme.

This is relevant because paediatric atopic dermatitis is a chronic inflammatory skin condition that can begin in infancy and place a long-term burden on patients and caregivers. Families may need safe and practical long-term treatment options, especially for younger children.

Devonian describes Thykamine as a potential non-steroidal therapeutic option for paediatric patients who require long-term disease management. The trial will be led by Dr Charles Lynde, Medical Director of the Lynde Institute for Dermatology and Associate Clinical Professor at the University of Toronto.

The authorisation enables Devonian to begin one of its most important clinical programmes for Thykamine, with paediatric dermatology centres expected to support enrolment and execution.