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CMS wins China approval for Lumirix in mild-to-moderate atopic dermatitis

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The topical JAK1/JAK2 inhibitor is now approved in China for patients aged two years and older, expanding beyond its earlier vitiligo indication.

China Medical System Holdings has announced that its subsidiary Dermavon Holdings has received approval from China's National Medical Products Administration for Lumirix, or ruxolitinib phosphate cream, in mild-to-moderate atopic dermatitis.

The product is approved for topical short-term and non-continuous chronic treatment in non-immunocompromised adult and paediatric patients aged two years and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

The new indication expands Lumirix beyond its earlier approval in January 2026 for vitiligo, when it became the first topical JAK inhibitor approved in China for that condition.

The atopic dermatitis application was included in the NMPA Center for Drug Evaluation's Priority Review pathway based on its qualification as a paediatric drug formulation aligned with children's physiological characteristics.

Clinical support for the approval included a randomised, double-blind, placebo-controlled Phase III study conducted in China.

At week eight, 63.0% of patients receiving Lumirix achieved an Investigator's Global Assessment score of 0 or 1 with at least a two-grade improvement from baseline, compared with 9.2% in the placebo group.

For the key secondary endpoint, 78.0% of Lumirix-treated patients achieved at least a 75% improvement in Eczema Area and Severity Index score, compared with 15.4% in the placebo arm.

Treatment-emergent adverse events were largely mild or moderate, with no treatment-emergent adverse events leading to discontinuation of study treatment.

Dermavon said the approval strengthens its broader "treatment + care" strategy in atopic dermatitis.

Its portfolio now spans topical treatment through Lumirix, the injectable biologic Comekibart for moderate-to-severe disease, oral small-molecule candidate CMS-D001, and daily skin-care products.

Atopic dermatitis is estimated to affect more than 54 million people in China, with mild-to-moderate disease accounting for the majority of cases.

Ruxolitinib phosphate cream was originally developed by Incyte and is marketed in the United States and Europe as Opzelura.

Dermavon secured exclusive development, registration and commercialisation rights for the product in mainland China, Hong Kong, Macau, Taiwan and 11 Southeast Asian countries under a 2022 licensing agreement with Incyte.

The new approval expands Dermavon's skin-health portfolio and could also strengthen commercial synergies across its existing dermatology products and pipeline.