Long-Term Safety and Disease Control With Ruxolitinib Cream in Atopic Dermatitis: Results From Two Phase 3 Studies

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Aboriginal Dermatitis (AD) is a highly pruritic inflammatory skin disease that is a significant public health burden in many countries. The pathogenesis of AD involves a complex interplay of genetic and environmental factors, with a strong association with atopy, which confers an increased risk of asthma, allergic rhinitis, and food allergies. Treatment options for AD are limited, and many patients experience persistent symptoms despite the use of conventional therapies. Therefore, there is a need for new, effective, and well-tolerated treatment options for AD.

Atopic dermatitis (AD) is a highly pruritic inflammatory skin disease that is associated with a range of symptoms, including redness, itching, and inflammation. The condition affects millions of people worldwide and can have a significant impact on quality of life. A total of 1249 patients were randomized in the VC period of the TRuE-AD1 (NCT02777500) and TRuE-AD2 (NCT03337516) studies. Ruxolitinib cream demonstrated statistically significant improvements in skin clearance and quality of life compared to vehicle. There were no clinically meaningful changes or trends in hematologic parameters.

No clinically meaningful changes or trends in hematologic parameters were observed over the treatment periods with ruxolitinib cream. In the long-term safety period, patients who previously applied vehicle were rerandomized 1:1 (blinded) to either ruxolitinib cream regimen (Vehicle to 0.75% RUX, n=101; Vehicle to 1.5% RUX, n=100). Any TEAE was reported by 91% of patients in the Vehicle to 0.75% RUX group and 95% of patients in the Vehicle to 1.5% RUX group. The most common TEAEs in the long-term safety period were dermatitis unrelated to study drug (14% in Vehicle to 0.75% RUX and 12% in Vehicle to 1.5% RUX) and reductions in affected BSA (9% in Vehicle to 0.75% RUX and 12% in Vehicle to 1.5% RUX). There were no deaths or unexpected serious adverse events.

In summary, ruxolitinib cream demonstrated statistically significant improvements in skin clearance and quality of life compared to vehicle. There were no clinically meaningful changes or trends in hematologic parameters. Ruxolitinib cream is a safe and effective treatment option for AD, particularly for patients who have not responded to conventional therapies. Future studies are needed to further evaluate the long-term safety and efficacy of ruxolitinib cream in a broader patient population.