

Dr Reddy's launches plaque psoriasis drug

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Dr Reddy's Laboratories has announced that its US subsidiary, Promius Pharma, Sernivo (betamethasone dipropionate) Spray, 0.05% in the U.S. Sernivo Spray, a prescription topical steroid approved by the Food and Drug Administration (FDA) in February of 2016, is indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older.

"We are proud to bring Sernivo Spray to patients across the U.S.," said Mr Raghav Chari, Executive Vice President, Proprietary Products Group at Dr Reddy's Laboratories, "This is another significant milestone for Promius Pharma. As an emerging leader in the dermatology space, we are committed to developing innovative treatment options."

Promius has conducted two multi-center, randomized, double-blind, vehicle-controlled clinical trials in subjects aged 18 years and older with moderate plaque psoriasis to evaluate the safety and efficacy of Sernivo Spray.

In both trials, randomized subjects applied Sernivo Spray or vehicle spray to the affected areas twice daily for 28 days. Enrolled subjects had body surface area of involvement between 10% to 20% and an Investigator Global Assessment (IGA) score of 3 (moderate). Efficacy was assessed as the proportion of subjects who were considered a treatment success (defined as having an IGA score of 0 or 1 [clear or almost clear] and at least a 2-scale reduction from baseline). Treatment success was achieved in significantly more subjects using Sernivo Spray than vehicle at both Day 15 and Day 29 across both studies. At Day 29 in Studies 1 and 2, Sernivo Spray achieved treatment success of 42.7% and 34.5% compared to vehicle success rates of 11.7% and 13.6%, respectively ($p < 0.001$).

"Plaque psoriasis can be a frustrating condition for patients and physicians alike. For patients, it is not only itchy and painful,

but depending on where on the body it occurs, it can be embarrassing for them and decrease their quality of life," said Dr Leon H. Kircik, clinical associate professor of dermatology at Indiana University School of Medicine. "As one of the researchers for Sernivo Spray, I'm excited to see this new treatment option added to our tool chest. With Sernivo Spray, I will now have a versatile option for patients that is easy to use in difficult to treat areas, like elbows and knees."