

Another FDA approval in Dr Reddy's kitty

08 February 2016 | News | By BioSpectrum Bureau

Another FDA approval in Dr Reddy's kitty



Dr Reddy's has announced that its US subsidiary, Promius Pharma has received approval for Sernivo (betamethasone dipropionate) Spray, 0.05 percent from the US Food and Drug Administration (US FDA). Sernivo Spray, a prescription topical steroid, is indicated for the treatment of mild to moderate plaque psoriasis in patients 18 years of age or older. The commercial launch of the product is planned for the coming quarter.

Commenting on the approval, Mr G V Prasad, co-chairman and CEO, Dr Reddy's Laboratories said, "The FDA approval of Sernivo Spray is a significant milestone for Promius, as it validates our committed efforts and resources to developing differentiated dermatology products from concept to commercial launch. We are delighted to receive a first round FDA approval of Sernivo Spray as we look to expand our portfolio of medical dermatology products available in the US market."

Promius has conducted two successful 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 percent, 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 than Vehicle at both Day 15 and Day 29 across both studies. At Day 29 in Studies 1 and 2, Sernivo achieved treatment success of 42.7 percent and 34.5 percent compared to vehicle success rates of 11.7 percent and 13.6 percent, respectively ($p < 0.001$).

Mr Raghav Chari, executive vice-president of Proprietary Products at Dr Reddy's and president of Promius Pharma said, "As an emerging leader in the dermatology space, we are committed to developing innovative treatment options and support services for clinicians and patients. The approval of Sernivo emphasizes our ongoing efforts and we look forward to a successful launch of Sernivo Spray in the coming quarter."