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Promius Pharma™ Receives FDA Approval for Sernivo (betamethasone dipropionate) Spray, 0.05%

Hyderabad, India, February 8, 2016

For Immediate Release

Hyderabad, India & Princeton, NJ, USA. February 8, 2016: Dr. Reddy's announced today that its US subsidiary, Promius Pharma™, LLC, U.S. (BSE: 500124, NSE: DRREDDY, NYSE: RDY), has received approval for Sernivo™ (betamethasone dipropionate) Spray, 0.05% from the U.S. Food and Drug Administration (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, 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%, 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% and 34.5% compared to vehicle success rates of 11.7% and 13.6%, respectively (p<0.001).

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."

Important Safety Information

In controlled clinical studies, the most common adverse reactions (≥1%) with 28 days of treatment with either Sernivo or placebo spray were: application site reactions, including pruritus, burning and/or stinging, pain, and atrophy. Do not use with occlusive dressings unless advised by a physician. Treatment should be limited to 4 weeks. Avoid use on the face, scalp, axilla, groin or other intertriginous areas or areas where skin atrophy is present. Not for oral, ophthalmic or intravaginal use.

Warnings/Precautions: Betamethasone dipropionate can produce reversible HPA axis suppression. Cushing's syndrome, hyperglycemia and unmasking of latent diabetes mellitus can result from systemic absorption of topical corticosteroids. Pediatric patients may be more susceptible to systemic toxicity when treated with topical corticosteroids and Sernivo is not indicated for patients less than 18 years of age.

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastro-intestinal, cardiovascular, diabetology, oncology, pain management and anti-infectives. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, Russia & CIS, Venezuela and India. For more information, log on to: www.drreddys.com
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About Promius Pharma: Promius Pharma is a wholly owned subsidiary of Dr. Reddy's Laboratories, one of largest and most respected pharmaceutical companies in the world. Our approach to product development relies heavily on converting deep insights gained from patients and physicians combined with strong collaborations with KOLs throughout the development continuum into highly innovative product concepts. Current R&D pipeline and commercialized products address the needs of patients with dermatological and neurological conditions. The company has successfully established a robust commercial infrastructure and leverages the extensive research and development capabilities available through its parent company. For more information, log on to www.promiuspharma.com.
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