PIPELINE PREVIEWS

Pipeline Previews brings to you information on the newest drugs and medical products as they become available to the dermatologic community. This department may include additional information from the manufacturers, plus reports from physicians who wish to share their clinical experience with these new products. In addition, we will inform our readers about the latest drugs receiving Food and Drug Administration (FDA) approval.

Dr. Reddy's Laboratories Receives FDA Tentative Approval for Zenavod™ (doxycycline) Capsules, 40 mg for the Treatment of Rosacea in Adults

Dr. Reddy's Laboratories has announced the U.S. Food and Drug Administration tentative approval for Zenavod™ (doxycycline) Capsules, 40 mg. Zenavod is a tetracycline-class drug indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.

Promius Pharma™, LLC, the U.S. subsidiary of India's Dr. Reddy's Laboratories will be responsible for commercializing Zenavod in the U.S. market.

The approval of the New Drug Application (NDA) is tentative because the FDA has determined that the drug meets all of the required quality, safety, and efficacy standards for approval, but it is subject to an automatic stay of final approval for up to 30 months pending a patent infringement process under the Drug Price Competition and Patent Term Restoration Act ("Hatch Waxman").

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

Dr. Reddy's Laboratories Ltd. announced that its U.S. subsidiary, Promius Pharma™, LLC, U.S., has received approval for Sernivo™ (betamethasone dipropionate) Spray, 0.05% from the U.S. Food and Drug Administration. 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.

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).