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Allergan receives FDA approval to market ACZONE (dapstone) Gel, 7.5% for acne treatment

Published on February 26, 2016 at 12:19 AM

Allergan plc (NYSE: AGN), a leading global pharmaceutical company, today announced that the Company has received approval from the U.S. Food and Drug Administration (FDA) to market ACZONE® (dapstone) Gel, 7.5%, a new prescription topical treatment for acne in patients 12 years of age and older. ACZONE® Gel, 7.5% delivers proven efficacy to treat both inflammatory and non-inflammatory acne, with a new concentration of dapstone in just once-a-day application.

"For the ACZONE® Gel, 7.5% pivotal trials, we studied 4,340 acne patients, demonstrating efficacy and tolerability. The new FDA product approval also offers just once-daily dosing and a new pump delivery system," said David Nicholson, Executive Vice President and President of Global R&D Brands at Allergan. "As part of Allergan's commitment to the medical dermatology space, we have truly raised the bar for ourselves in efforts to offer an effective acne product to address physician and patient needs."

In clinical trials of ACZONE® Gel, 7.5%, safety and efficacy were assessed in two identically designed, randomized, multi-centered, double-blind, vehicle-controlled 12-week studies. A total of 4,340 acne patients were randomized to receive either ACZONE® Gel, 7.5% (n=2162) or vehicle (n=2178). The majority of patients (99%; n=4339) had moderate acne, with a baseline score of 3 on the Global Acne Assessment Score (GAAS). ACZONE® Gel, 7.5% was approved based on co-primary endpoints of the GAAS and lesion counts (20 to 50 inflammatory and 30 to 100 non-inflammatory lesions at baseline). At week 12, inflammatory lesions were reduced by 15.8 lesions (54.6%; n=2162) vs 13.9 lesions with vehicle (48.1%; n=2178), and non-inflammatory lesions were reduced by 20.7 lesions (45.1%) vs 18.0 lesions with vehicle (39.4%). The GAAS success rate in patients was 29.8% (n=2162) vs 21.1% with vehicle (n=2178).

In addition to efficacy, ACZONE® Gel, 7.5% has a proven tolerability profile. Out of 2161 patients who used ACZONE® Gel, 7.5%, 1.1% experienced mild application-site dryness vs 1.0% with vehicle (n=2175), and 0.9% experienced pruritus vs 0.5% with vehicle.

"ACZONE® Gel, 7.5%, is a new once-daily option that was shown to have significant improvement in patients' acne after 12 weeks of use," said Linda Stein Gold, MD, Director of Dermatology Clinical Research, Division Head of Dermatology at Henry Ford Health System in Michigan and a lead investigator in the studies. "This new formulation was well-tolerated, which is especially important to many of my female patients."

ACZONE® Gel, 7.5% will be available in May 2016 nationwide.

Approved Use

ACZONE® (dapstone) Gel, 7.5% is a prescription medicine used on the skin (topical) to treat acne in people 12 years and older.

Source:
Allergan plc
