Journal of the American Academy of Dermatology Publishes ZORYVE (roflumilast) Foam, 0.3% Results for Seborrheic Dermatitis from Pivotal Phase 3 Trial

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- Novel steroid-free topical foam effectively controls seborrheic dermatitis
- Once-daily ZORYVE® (roflumilast) topical foam, 0.3%, is approved to treat seborrheic dermatitis in individuals 9 years of age and older

WESTLAKE VILLAGE, Calif., Jan. 29, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that the *Journal of American Academy of Dermatology* (JAAD) published positive results from the pivotal Phase 3 STRATUM trial evaluating ZORYVE (roflumilast) foam, 0.3% as a once-daily steroid-free treatment for seborrheic dermatitis. The article was published online, and found that treatment with ZORYVE foam was superior to vehicle, with 80% of individuals achieving the primary efficacy endpoint of Investigator Global Assessment (IGA) Success and 51% of individuals reaching complete clearance at Week 8. ZORYVE foam was approved by the U.S. Food and Drug Administration (FDA) for treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older in December 2023 and is the first drug approved for seborrheic dermatitis with a new mechanism of action in over two decades.

“Despite being very common, seborrheic dermatitis has traditionally been a disease with limited treatment options. It also can have a significant impact on quality of life,” stated Dr. Andrew Blauvelt, MD, MBA, lead study author and investigator at the Oregon Medical Research Center. “The publication of the Phase 3 STRATUM study results in the *Journal of American Academy of Dermatology* further validates the significance of roflumilast foam as a new treatment option for seb derm, one that provides treatment success in eight of ten patients, along with significant and rapid improvements in key signs and symptoms of disease, as early as two weeks. These results highlight the effectiveness and safety of roflumilast foam, a steroid-free treatment and the first novel mechanism of action approved for seb derm in two decades. It should end suffering from this long-neglected condition.”

“Seborrheic dermatitis is challenging to manage, and often people with the disease require several different treatments for different areas of their body. Our focus has been to simplify the treatment of seborrheic dermatitis with an effective once-daily steroid-free foam that is suitable for use anywhere on the body for any duration and on all hair and skin types,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. “We are pleased that this manuscript is now available to provide dermatology clinicians with a greater understanding of the clinical data supporting ZORYVE foam as a newly approved treatment option for their patients.”

The STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis (STRATUM) was a parallel group, double-blind, vehicle-controlled study evaluating the safety and efficacy of ZORYVE (roflumilast) foam, 0.3% in seborrheic dermatitis. The trial enrolled 457 adults and adolescents with moderate to severe seborrheic dermatitis affecting up to 20% body surface area (BSA), including the scalp, face, trunk, and/or intertriginous areas.

- The STRATUM study met its primary endpoint, with 80% of roflumilast foam treated individuals reaching IGA Success rate at Week 8 (79.5% ZORYVE foam vs. 58.0% vehicle; $p<0.0001$). IGA Success was defined as an IGA score of clear or almost clear plus a ≥2 grade improvement from baseline.
- Improvement was seen early, with roflumilast foam demonstrating a statistically significant improvement compared to vehicle on IGA Success at Week 2, the first timepoint assessed in STRATUM.
- In addition, 50.6% of individuals in the roflumilast foam treated arm reached complete clearance (IGA=0) at Week 8.
- Roflumilast foam also demonstrated statistically significant improvement over vehicle on all secondary endpoints, including itch, scaling, and erythema (redness).
    - More than 60% of individuals achieved a ≥4-point reduction in itch at Week 8 as measured by Worst Itch-Numerical Rating Score (62.8% roflumilast foam vs. 40.6% vehicle; $p=0.0001$), and significant improvements in itch were also reported at Week 2 and Week 4.
    - Individuals treated with ZORYVE foam reported a 28% improvement in itch from baseline in 48 hours (compared to 13% on vehicle nominal $p=0.0024$).
    - More than 50% of individuals treated with ZORYVE foam achieved an erythema (redness) score of 0, and more than 50% achieved a scaling score of 0, at Week 8.
- Treatment with ZORYVE foam demonstrated a significantly larger improvement in patient reported outcomes as early as Week 2 as measured through Dermatology Life Quality Index (DLQI), with improvements maintained through Week 8.

ZORYVE foam was well-tolerated with a favorable safety and tolerability profile. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar between active treatment and vehicle, with most TEAEs assessed as mild to moderate severity. There were no treatment-related Serious Adverse Events (SAEs). The most common adverse reactions (≥1%) reported, per the prescribing information, include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio including two U.S. FDA approved products that harness our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis' dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including scalp and body psoriasis, atopic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and X.

INDICATION
ZORYVE foam, 0.3%, is indicated for treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION
ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see full Prescribing Information.

Forward-Looking Statements
Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential of ZORYVE foam to simplify disease management for care of seborrheic dermatitis; the potential of real-world use results of ZORYVE foam, as well as the commercial launch of ZORYVE foam in seborrheic dermatitis. These statements are subject to substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 28, 2023, as well as any subsequent filings with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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