ZORYVE® (Roflumilast) Topical Foam, 0.3% Clears Seborrheic Dermatitis in Individuals Who Previously Reported an Inadequate Response to Topical Steroids

January 14, 2024

- New subgroup analysis from STRATUM study shows that individuals with an inadequate response, contraindication, or intolerance to steroids were 3.5 times more likely to achieve IGA Success with ZORYVE foam than an identical vehicle
- ZORYVE foam provided rapid and significant improvement in quality of life scores in patients 17 years and older
- Data presented at the 2024 Winter Clinical Dermatology Conference - Hawaii

WESTLAKE VILLAGE, Calif., Jan. 14, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced a new subgroup analysis highlighting that adults and adolescents with seborrheic dermatitis who are contraindicated, intolerant, or unresponsive to topical steroids were 3.5 times more likely to achieve IGA Success with ZORYVE® (roflumilast) topical foam, 0.3%, compared to vehicle (78.8% ZORYVE foam; 48.3% vehicle; p<0.001)[i]. ZORYVE foam is a once-daily steroid-free topical for use in all skin and hair types that effectively clears and controls seborrheic dermatitis. Data were presented at the 2024 Winter Clinical Dermatology Conference – Hawaii held January 12-17, 2024, in Honolulu.

Treatment with ZORYVE foam significantly increased the odds of achieving a meaningful improvement in quality of life at Weeks 2, 4, and 8, compared to vehicle as measured by the Dermatology Life Quality Index (DLQI) (odds ratio (OR) 6:97; 95% confidence interval (CI) 3.97, 12.24; p<0.001). DLQI was measured in patients 17 years of age and older. 72.5% of individuals achieved a minimally important difference[ii] in DLQI score as early as 2 weeks, increasing to 86.6% at the end of the study, Week 8 (compared to 28.1% p=0.001 and 53.6% p=0.001 for vehicle, respectively).

“Seborrheic dermatitis is a chronic, recurrent skin disease that can negatively impact the quality of life of affected individuals, including their self-esteem, emotional well-being, and ability to perform everyday tasks like work or social activities. This new analysis quantifies a meaningful improvement in both the signs and symptoms of seborrheic dermatitis as well as quality of life for individuals treated with ZORYVE foam,” said Matthew Zirwas, MD, founder of the Bexley Dermatology Research Clinic and an investigator in the trial. “As a practitioner, this large subgroup analysis provides me with the confidence to include ZORYVE foam as an important new treatment in my armamentarium to prescribe to my patients, including those who have failed topical steroids which are commonly prescribed for seb derm.”

“This subgroup analysis builds upon the existing evidence for ZORYVE foam as an effective once-a-day treatment option for use in all skin and hair types to clear and control seborrheic dermatitis, including among those who previously experienced inadequate response or intolerance to topical steroids,” said Patrick Burnett, MD, PhD, FAAD, chief medical officer of Arcutis. “As the first topical drug approved with a new mechanism of action for this condition in 20 years, ZORYVE foam represents an important advancement in treatment and addresses a truly significant need in this population.”

ZORYVE foam was well-tolerated with a favorable safety and tolerability profile. 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). Overall, the most common adverse reactions (≥1%) included nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

The STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis (STRATUM) evaluated ZORYVE foam vs vehicle once daily for 8 weeks. The subgroup analysis included 189 adults and adolescents 9 years of age and older with moderate-to-severe seborrheic dermatitis who reported an inadequate response, intolerance, or contraindication to steroids prior to enrollment in the STRATUM study (41.4% of the total study population).

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 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.

INDICATIONS
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%) for ZORYVE foam include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see full Prescribing Information for ZORYVE foam.

ZORYVE is for topical use only and not for ophthalmic, oral, or intervaginal use.

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 for ZORYVE to simplify disease management for care of seborrheic dermatitis; the potential of real-world use results of roflumilast foam, as well as the commercial launch of ZORYVE 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Derek Cole
Investor Relations Advisory Solutions
derek.cole@iradvisory.com

---

[i] IGA success was defined as at least a 2-point reduction in IGA score from baseline and an IGA score of 0 (clear) or 1 (almost clear)
[ii] Meaninful important difference defined as at least a 4-point reduction in baseline DLQI score, and achievement of a DLQI score of 0 or 1