Arcutis Announces FDA Acceptance of New Drug Application for Roflumilast Foam 0.3% for the Treatment of Seborrheic Dermatitis in Individuals Aged 9 Years and Older

April 18, 2023

- FDA has set a target action date of December 16, 2023
- NDA supported by positive efficacy and safety data from the Phase 2 and pivotal Phase 3 trials of roflumilast foam
- If approved, roflumilast foam would be the first topical drug for seborrheic dermatitis with a new mechanism of action in over two decades

WESTLAKE VILLAGE, Calif., April 18, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage company focused on developing meaningful innovations in immuno-dermatology, today announced the U.S. Food and Drug Administration (FDA) has accepted for review the company's new drug application (NDA) for roflumilast foam 0.3% for the treatment of seborrheic dermatitis in individuals 9 years of age and older. The application was assigned a Prescription Drug User Fee Act (PDUFA) target action date of December 16, 2023.

"Seborrheic dermatitis has long been a disease in need of its own treatment," said Neal Bhatia MD, Director of Clinical Dermatology at Therapeutics Clinical Research and one of the investigators for Arcutis. "Some of the biggest challenges of current treatments have not only been lack of efficacy and consequences from long-term use, but also the limitations that affect adherence, especially the inability to treat both hair- and non-hair-bearing areas. Roflumilast foam was designed to address these shortcomings, as a once-daily, steroid-free topical drug that can be used chronically anywhere on the body. Dermatologists will be excited to incorporate roflumilast foam, if approved, as a new standard of care for those living with seborrheic dermatitis."

Roflumilast foam is an investigational once-daily, topical formulation of a highly potent and selective phosphodiesterase type 4 (PDE4) inhibitor being developed to treat inflammatory dermatoses, particularly in hair-bearing areas of the body such as the scalp, face, and trunk.

Seborrheic dermatitis affects more than 10 million people in the U.S., and is a common, chronic, and recurrent inflammatory skin disease that causes red patches covered with large, greasy, flaking yellow-gray scales, and persistent itch. Seborrheic dermatitis occurs most often in areas of the body with oil-producing (sebaceous) glands, including the scalp, face (especially on the nose, eyebrows, ears, and eyelids), upper chest, and back.

"The acceptance of the NDA for roflumilast foam marks a major milestone toward our goal of bringing a steroid-free, topical foam treatment option to market, addressing a significant unmet need for individuals living with seborrheic dermatitis," said Frank Watanabe, President and CEO of Arcutis. "If approved, roflumilast foam would be the first topical drug with a new mechanism of action for this condition in over two decades, highlighting the unique formulation and deep dermatological expertise that Arcutis brings to immuno-dermatology. We look forward to continuing our work with the FDA over the coming months and are preparing commercial efforts for the anticipated approval and launch."

The NDA is supported by positive results from Arcutis' Phase 2 and pivotal Phase 3 trials in seborrheic dermatitis. The STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis (STRATUM) was the pivotal Phase 3, parallel group, double-blind, vehicle-controlled study evaluating the safety and efficacy of roflumilast foam 0.3% in seborrheic dermatitis. The STRATUM study met its primary endpoint with an Investigator Global Assessment (IGA) Success rate of 79.5% in roflumilast foam-treated individuals compared to 58.0% ($P<0.0001$) in those treated with vehicle at Week 8. Improvement with roflumilast foam was seen early, with roflumilast demonstrating a statistically significant improvement compared to vehicle on IGA Success at Week 2, the first timepoint assessed. In addition, 51.3% of individuals in the roflumilast foam treated arm reached complete clearance at Week 8.

The study also demonstrated statistically significant improvement over vehicle on all secondary endpoints, including itch, scaling, and erythema (redness). More than 60% of individuals achieved an itch response at Week 8 (62.8% roflumilast foam vs 40.6% vehicle; $p=0.0001$), and significant improvements in itch were reported at Week 2 and Week 4.

Roflumilast 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). In the combined Phase 2 and Phase 3 studies, over 90% of patients who were randomized to roflumilast foam in the study completed the full eight weeks of treatment, and there were few discontinuations due to adverse events (0.9% and 2.2% in the roflumilast foam and vehicle groups, respectively). Overall, the most common adverse events occurring in ≥1% of subjects in the combined phase 2 and phase 3 study populations included nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

About Topical Roflumilast
Arcutis is developing topical cream and foam formulations of roflumilast, a highly potent and selective PDE4 inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for multiple dermatologic conditions. PDE4 – an established target in dermatology – is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators. Roflumilast foam is a once-daily foam formulation of roflumilast which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis.

Roflumilast cream 0.3% (ZORYVE®) is approved by the FDA for the topical treatment of plaque psoriasis in adults and adolescents.

About ZORYVE
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

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

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full Prescribing Information.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is an early 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 that harnesses 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, seborrheic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

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 and timing for roflumilast foam to be approved by the FDA for the treatment of adults and adolescents with seborrheic dermatitis, the potential to use roflumilast foam over a long period of time, or chronically, the potential to use roflumilast foam anywhere on the body, including the face and scalp, and the potential for roflumilast foam to advance the standard of care in seborrheic dermatitis and other inflammatory dermatological conditions. 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 the 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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