Arcutis Submits Topical Roflumilast Foam 0.3% New Drug Application to the FDA for the Treatment of Seborrheic Dermatitis in Adults and Adolescents

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- Seborrheic dermatitis is an inflammatory skin disease affecting more than 10 million individuals in the United States
- If approved, roflumilast foam would be the first topical drug for seborrheic dermatitis with a new mechanism of action in over two decades
- In a pivotal Phase 3 trial, 80% of individuals treated with roflumilast foam achieved IGA Success at Week 8
- Roflumilast foam was well-tolerated with a favorable safety and tolerability profile

WESTLAKE VILLAGE, Calif., Feb. 21, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage company focused on developing meaningful innovations in immuno-dermatology, today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for roflumilast foam 0.3% for the treatment of moderate to severe seborrheic dermatitis in adults and adolescents. Roflumilast foam 0.3% is an investigational once-daily topical foam 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 can be particularly difficult to treat as it primarily presents on the face and hair-bearing areas of the body such as the scalp, and often requires individuals to use multiple treatments. Arcutis recognizes the urgent need for a new therapy that could enable symptom control, easier management, and increased adherence," said Patrick Burnett M.D., Ph.D, F.A.A.D., Chief Medical Officer at Arcutis. "Roflumilast foam, which is being developed as an easy-to-use, steroid free, once-daily topical treatment, has been shown in clinical trials to be effective and well tolerated. If approved, roflumilast foam has the potential to become the new standard of care for those living with seborrheic dermatitis."

Seborrheic dermatitis affects more than 10 million people in the United States, and is a common, chronic, or recurrent inflammatory skin disease that causes red, itchy patches covered with large, greasy, flaking yellow-gray scales. 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.

"Topical therapies are considered the cornerstone of treatment of seborrheic dermatitis, but currently available therapies come with multiple tradeoffs, such as limited duration of use, the need for multiple applications a day to affected areas, skin irritation, and the inability to use on both hair- and non-hair-bearing areas of the body, making for a complex care routine," said Frank Watanabe, President and CEO of Arcutis. "There has not been a once-daily steroid-free topical prescription treatment approved for seborrheic dermatitis in over a decade. New steroid-free options are needed that can be used chronically anywhere on the body, enabling people with seborrheic dermatitis to manage their disease more easily and consistently."

The submission is supported by positive results from Arcutis' pivotal Phase 3 trial. The STudy of Roflumilast foam Applied Topically for the redUction of seborrheic derMatitis (STRATUM) was a Phase 3, parallel group, double blind, vehicle-controlled study evaluating the safety and efficacy of roflumilast foam 0.3%. Roflumilast met its primary endpoint with an 'IGA Success' rate of 79.5% compared to a vehicle rate of 58.0% (P<0.0001) at Week 8. IGA Success was defined as an IGA score of clear or almost clear plus a ≥2 grade improvement from baseline. Improvement with roflumilast foam was seen early, with roflumilast demonstrating a statistically significant improvement from vehicle on IGA Success at Week 2, the first timepoint assessed. In addition, 51.3% of individuals in the roflumilast foam treated arm reached clear at Week 8.

The study also demonstrated statistically significant improvements 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), with significant improvements 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). Over 90% of patients who were randomized to roflumilast foam in the study completed the full eight weeks, and there were few discontinuations due to adverse events (0.7% and 2.0% in the roflumilast foam and vehicle groups, respectively). Overall, the most common adverse events in the STRATUM study population included COVID-19, urinary tract infection, nasopharyngitis, and nausea.

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 for roflumilast foam to be approved 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, anticipated acceptance of the NDA and subsequent FDA approval, and the potential for roflumilast foam to advance the standard of care in seborrheic dermatitis and other inflammatory dermatological conditions. These statements involve 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 and you should not place undue reliance on our 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 22, 2022, as amended, 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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