Arcutis Biotherapeutics Showcases Pivotal DERMIS-1 and -2 Phase 3 Trial Data for Topical Roflumilast Cream (ARQ-151) in Plaque Psoriasis at EADV Spring Symposium 2021

May 6, 2021

- *Data show roflumilast produced robust efficacy compared to vehicle in both Phase 3 studies on the primary efficacy endpoint of IGA success at eight weeks*
- *Roflumilast also demonstrated statistically significant improvements over vehicle in the key secondary endpoints of I-IGA success, PASI-75, and reduction in itch as measured by WI-NRS*
- *Improvement in itch occurred as early as two weeks and improved consistently through week eight*
- *Roflumilast safety and tolerability were similar to vehicle*

WESTLAKE VILLAGE, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced the presentation of new data from the DERMIS-1 and DERMIS-2 pivotal Phase 3 studies evaluating roflumilast cream (ARQ-151) as a potential once daily, topical treatment for chronic plaque psoriasis at the European Association of Dermatology and Venereology (EADV) Spring Symposium. Roflumilast cream is a once daily topical formulation of roflumilast, a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4).

Both Phase 3 trials achieved the primary efficacy endpoint of Investigator Global Assessment (IGA) Success at week eight, with significantly more patients treated with roflumilast cream 0.3% reaching IGA success compared to the control group of vehicle-treated patients (DERMIS-1: 42.4% vs. 6.1%; DERMIS-2: 37.5% vs. 6.9%, respectively, P<0.001 for both). IGA success is defined as clear or almost clear with at least a 2-grade improvement from baseline.

“While nearly 90 percent of people with plaque psoriasis rely upon topical therapies, unfortunately, existing options often have significant shortcomings that force these patients and their dermatologists to make trade-offs between efficacy, safety, and tolerability,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “We are excited to share these Phase 3 trial findings, which we believe reinforce roflumilast cream as a potential topical treatment that is uniquely suited to address this unmet need and help those who have been struggling to treat their condition.”

Roflumilast also demonstrated statistically significant improvements over vehicle in key secondary endpoints, including the treatment of psoriasis presenting in intertriginous areas (i.e., where two skin areas may touch or rub together), as measured by intertriginous-IGA (I-IGA) success (clear or almost clear with at least a 2-grade improvement from baseline). When plaque psoriasis presents in intertriginous areas, it can be particularly challenging to treat, with physicians often needing to prescribe a regimen of multiple medications for a single patient. In the Phase 3 trials, roflumilast was highly effective for intertriginous plaques, with significantly more roflumilast-treated patients reaching I-IGA success at week eight than vehicle-treated patients (DERMIS-1: 71.2% vs. 13.8%, P<0.0001; DERMIS-2: 68.1% vs 18.5%, P=0.0004), with the vast majority of these patients achieving I-IGA=0 (clear).

“Historically, there has been a significant lack of innovation in the development of topical treatments for plaque psoriasis, with no novel nonsteroidal topical therapies approved in more than two decades,” said Mark Lebwohl, MD, Professor and Dean for Clinical Therapeutics, Icahn School of Medicine at Mount Sinai, and participant in the trial. “This needs to be remedied, as those who suffer from the burden of chronic plaque psoriasis and their doctors need and deserve better options. These data, which demonstrate a robust efficacy and safety profile for roflumilast cream, represent a hopeful sign for the possibility of advancing the care of this condition.”

Other key Phase 3 findings include:

- Roflumilast was statistically superior to vehicle for improvement of psoriasis at all timepoints as measured by the Psoriasis Area Severity Index (PASI). Across both trials, approximately 40% of patients achieved a 75% reduction in PASI scores (PASI-75) by week eight (DERMIS-1: 41.6% vs 7.6%; DERMIS-2: 39.0% vs 5.3%, P<0.0001).
- Patients with clinically significant itch, as measured by a baseline Worst Itch-Numeric Rating Scale (WI-NRS) ≥4, achieved a 4-point reduction in WI-NRS at week eight (DERMIS-1: 67.5% vs 26.8%; DERMIS-2: 69.4% vs 35.6%, P<0.0001). Itch improvement was notable by two weeks, the earliest timepoint measured (DERMIS-2: P=0.0026), with consistent improvements achieved through week eight.
- Roflumilast safety and tolerability were similar to vehicle, including pooled rates of treatment-related treatment-emergent adverse events (AEs) (3.9% roflumilast vs. 3.6% vehicle), any AE leading to discontinuation (1.0% roflumilast vs 1.3% vehicle) and application site pain (1.0% roflumilast vs 0.3% vehicle). There were no treatment-related serious AEs, and local tolerability was highly favorable for roflumilast as reported by patient and investigator assessment of irritation, burning, and stinging.

The “Trials of P **DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque Psorias**IS**” One and Two (or DERMIS-1 and DERMIS-2) were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which roflumilast 0.3% cream or matching vehicle cream were applied once daily for 8 weeks to subjects age 2 years and above with mild, moderate, or severe chronic plaque psoriasis involving between 2% and 20% body surface area. DERMIS-1 enrolled 439 subjects, and DERMIS-2 enrolled 442 subjects. The primary endpoint of the studies was Investigator Global Assessment (IGA) Success at week 8. Multiple secondary endpoints were also evaluated, including intertriginous-IGA (I-IGA) Success, and improvements in Psoriasis Area Severity Index (PASI), itch as measured by the WI-NRS and patient perceptions of symptoms as

measured by the Psoriasis Symptoms Diary (PSD).

For more information, visit https://www.arcutis.com or follow the company on LinkedIn and Twitter. Join the conversation with the hashtag #EADVSymposium.

Disclosure: Dr. Lebwohl has been a paid consultant and researcher for Arcutis.

About Plaque Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately 8.6 million patients in the United States. About 90% of patients develop plaque psoriasis, which is characterized by raised, red areas of skin covered with a silver or white layer of scale. Psoriatic plaques can appear on any area of the body, but most often appear on the scalp, knees, elbows, trunk, and limbs, and are often itchy and sometimes painful. Plaques in certain anatomical areas present particular treatment challenges, including the face, elbows and knees, scalp, and intertriginous regions such as the groin, axillae and inframammary areas.

About Topical Roflumilast Cream
Roflumilast Cream is a topical cream formulation of a highly potent and selective PDE4 inhibitor (roflumilast). Roflumilast has been approved by the U.S. Food and Drug Administration (FDA) for oral treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency (25- to 300-fold) than the two other FDA-approved PDE4 inhibitors. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the FDA for the topical treatment of atopic dermatitis or the systemic treatment of plaque psoriasis.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a late-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology. The company is leveraging recent advances in immunology and inflammation to develop differentiated therapies against biologically validated targets to solve persistent treatment challenges in serious diseases of the skin. Arcutis' robust pipeline includes four novel drug candidates currently in development for a range of inflammatory dermatological conditions. The company's lead product candidate, topical roflumilast, has the potential to revitalize the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit https://www.arcutis.com or follow the company on LinkedIn and Twitter.

Forward-Looking Statements
This press release contains "forward-looking" statements, including, among others, statements regarding the potential for roflumilast to revolutionize the standard of care in plaque psoriasis 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 the clinical development process and regulatory approval process, the timing of regulatory filings, and our ability to defend our intellectual property. For a further description of the risks and uncertainties applicable to our business, see the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 16, 2021, as well as any subsequent filings with the SEC. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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