Arcutis Biotherapeutics Presents New Positive Data from Phase 2 Studies of ARQ-151 (Topical Roflumilast Cream) in Chronic Plaque Psoriasis and Atopic Dermatitis

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- In Phase 2b study of patients with plaque psoriasis, roflumilast cream demonstrated rapid and clinically significant reduction in the severity and burden of itch and itch-related sleep loss as well as rapid improvement in patient-reported symptom burden
- Phase 2 proof-of-concept study in atopic dermatitis underscores potential of roflumilast cream as once-daily treatment for this common condition
- Roflumilast cream was safe and well-tolerated by psoriasis and atopic dermatitis patients in both Phase 2 studies, further highlighting its differentiated tolerability profile
- Company highlights study results in presentations at the European Academy of Dermatology and Venereology Virtual Congress, Society of Dermatology Physician Assistants Digital 2020 conference, and virtual 2020 Fall Clinical Dermatology Conference

WESTLAKE VILLAGE, Calif., Nov. 02, 2020 (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 reported new positive data from previously announced Phase 2 studies of ARQ-151 (topical roflumilast cream) in patients with chronic plaque psoriasis and atopic dermatitis. The data is being presented at the European Academy of Dermatology and Venereology (EADV) Virtual Congress (EADV Virtual), Society of Dermatology Physician Assistants (SPDA) Digital 2020 conference, and virtual 2020 Fall Clinical Dermatology Conference.

Roflumilast cream, a potent phosphodiesterase-4 (PDE-4) inhibitor, is being investigated as a once-daily topical treatment for chronic plaque psoriasis and atopic dermatitis. In two virtual presentations, Arcutis shared data from a Phase 2b study on the efficacy of roflumilast cream on itch, a highly prevalent and frequently bothersome symptom of chronic plaque psoriasis, and on improving the burden of typical plaque psoriasis symptoms. In a third presentation, Arcutis highlighted results from a Phase 2 proof-of-concept study on the short-term safety and efficacy of roflumilast cream in patients with mild-to-moderate atopic dermatitis.

“The results from our Phase 2 studies highlight the potential of roflumilast cream as a best-in-class topical PDE4 inhibitor for chronic plaque psoriasis and atopic dermatitis,” said Patrick Burnett, M.D., Ph.D., FAAD, Arcutis’ Chief Medical Officer. “The Phase 2b psoriasis study data provide clinical evidence of roflumilast cream’s ability to reduce the burden of itch and improve typical symptoms in patients with plaque psoriasis. In addition, the encouraging efficacy results and safety profile in our Phase 2 proof-of-concept of roflumilast cream in atopic dermatitis provide a solid foundation for our upcoming pivotal Phase 3 studies.”

Results from the Phase 2b Study in Plaque Psoriasis

In the Phase 2b study, 331 patients were randomized to roflumilast 0.3% (n=109), roflumilast 0.15% (n=113), or vehicle (n=109). At baseline, patients had to score ≥2 on the Investigator Global Assessment (IGA) scale and ≥2 on the modified Psoriasis Area and Severity Index. The primary endpoint was achievement of clear or almost clear skin based on IGA 0 or 1 at Week 6.

Itch was assessed at baseline and throughout the 12-week trial using various patient-reported outcome measures, including itch severity and itch-related sleep loss. The study showed that treatment with roflumilast cream resulted in a rapid and clinically significant reduction in the severity and burden of itch compared to vehicle. In the roflumilast 0.3% group, significant itch reduction occurred by week 2 as compared with vehicle and continued through week 12 with 63% of patients achieving a clinically meaningful itch reduction. Reduction in itch also resulted in significant improvement in sleep loss by week 6 and continued through week 12.

The Phase 2b study also assessed the efficacy of roflumilast cream in improving the burden of signs and symptoms of plaque psoriasis, including stinging, burning, skin cracking, pain, and scaling. Both doses of once-daily roflumilast cream led to rapid and robust improvements in symptom burden and quality of life in the patient population. The study results showed statistically significant improvements for both roflumilast doses compared with vehicle were seen in burden of individual patient-reported psoriasis-related signs and symptoms of scaling by Week 2; stinging, skin cracking, and pain by Week 4; and burning by Week 6. All reported improvements in individual psoriasis-related signs and symptoms were maintained through Week 12 with a mean decrease from baseline in the overall Patient Symptom Diary (PSD) Score of 42 and 44 in the roflumilast 0.3% and 0.15% groups, respectively.

Roflumilast cream was well-tolerated by patients in the Phase 2b study. The rate of application site pain was low and similar to vehicle. 97% of adverse events were mild or moderate.

Results from the Phase 2 Proof-of-Concept Study in Atopic Dermatitis

In the Phase 2 proof-of-concept study in atopic dermatitis (AD), 136 patients were randomized to roflumilast 0.15%, roflumilast 0.05% or vehicle once-daily for 4 weeks. Patients had 1.5–35% body surface area (BSA) affected by AD, with a validated investigator global assessment AD (vIGA-AD) score of 2 (mild) or 3 (moderate), and eczema area and severity index (EASI) score of ≥5. The primary efficacy endpoint was absolute change from baseline in EASI score at Week 4.

Study results showed that once-daily roflumilast cream demonstrated efficacy when compared to vehicle in AD. Although the primary endpoint in this proof of concept study showed a trend towards, but did not reach statistical significance, statistical significance for other efficacy endpoints was reached. Statistically significant improvements compared with vehicle were observed at Week 4, including 72.3% EASI improvement and >50% of patients achieving *clear* or *almost clear* skin on vIGA-AD for roflumilast cream 0.15%. Roflumilast cream was well tolerated, with a low rate of application site reactions, and no local irritation.

The virtual presentations of Arcutis' Phase 2b and Phase 2 proof-of-concept studies of roflumilast cream given at the EADV Virtual Congress (October 29-31, 2020) and the 2020 Fall Clinical Dermatology Conference and SPDA DIGITAL 2020 (October 29 – November 1, 2020), are available for on-demand viewing using the links below and under Scientific Publications on the Arcutis website:

- Roflumilast Cream (ARQ-151) Improved Itch Severity and Itch-related Sleep Loss in Adults With Chronic Plaque Psoriasis in a Phase 2b Study: **EADV Virtual Congress; 2020 Fall Clinical; SPDA DIGITAL 2020**
- Roflumilast Cream (ARQ-151) 0.15% and 0.3% Improved Symptom Burden in Adults With Chronic Plaque Psoriasis in a Phase 2b Study: **EADV Virtual Congress; 2020 Fall Clinical; SPDA DIGITAL 2020**
- The Safety and Efficacy of Roflumilast Cream 0.15% and 0.05% in Atopic Dermatitis: Phase 2 Proof-of-Concept Study: **EADV Virtual Congress; 2020 Fall Clinical; SPDA DIGITAL 2020**

About Atopic Dermatitis

Atopic dermatitis (AD) is the most common type of eczema, occurring in approximately six percent of the U.S. population. AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms and legs, and the rash can cover significant areas of the body, in some cases half of the body or more. Disease onset is most common by 5 years of age, and the Company estimates that approximately 60% of patients suffering from AD are pediatric patients. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Given that most of the patients are pediatric, the safety and tolerability of AD therapies are paramount.

About 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 Arcutis - Bioscience, applied to the skin.

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 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 ARQ-151's potential as a "Best-in-Class" PDE4 inhibitor, ARQ-151's potential as a treatment for atopic dermatitis, ARQ-151's potential as a treatment for plaque psoriasis and whether positive results in Phase 2 studies are indicative of potential outcomes in future studies. 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-Q filed with U.S. Securities and Exchange Commission (SEC) on August 11, 2020, 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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