



Preliminary Data from Long-Term Safety Study Support Chronic Use of ARQ-151 (Topical Roflumilast Cream) as a Potential Treatment for Plaque Psoriasis

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- Once-daily roflumilast demonstrated favorable safety and tolerability over 52 to 64 weeks of treatment
- At 52 to 64 weeks of treatment, 44% of subjects had attained an IGA of clear or almost clear
- Preliminary data further support the potential of roflumilast as a novel, once-daily, chronic topical treatment for plaque psoriasis, including intertriginous psoriasis

WESTLAKE VILLAGE, Calif., July 31, 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 announced preliminary results for the first cohort of 223 subjects from its ongoing Phase 2 long-term safety study evaluating ARQ-151 (topical roflumilast cream) 0.3% as a potential once-daily chronic topical treatment for plaque psoriasis. Arcutis now expects to have topline data for the full study population of 332 subjects from both cohorts in the first quarter of 2021.

The first cohort of the long-term safety study includes subjects who elected to continue open-label treatment following their participation in the double-blind, randomized Phase 2b study of roflumilast cream in plaque psoriasis, the results from which were recently published in the [New England Journal of Medicine](#). In this group of subjects, roflumilast cream 0.3% applied once daily for up to a total of 52 to 64 weeks demonstrated favorable safety and tolerability over the long-term treatment period, consistent with what was seen in the parent Phase 2b study. At 52 to 64 weeks of treatment, 44% of subjects had an Investigator Global Assessment (IGA) of clear or almost clear, compared to 38% of subjects at 12 weeks of treatment with ARQ-151 0.3% in the parent Phase 2b study. Additionally, of the subjects in the parent Phase 2b study who received ARQ-151 0.3%, attained an IGA of clear or almost clear at 12 weeks, and continued on treatment in the long-term safety study, 68% had an IGA of clear or almost clear at the end of 64 weeks of treatment. Subjects who had received vehicle in the parent Phase 2b study but then received active treatment in the long-term safety study achieved IGA of clear or almost clear at a similar percentage and in a similar time course as subjects who received active treatment in the parent study. Of the 223 subjects included in this analysis, 73% have completed the full 52 weeks of open label treatment.

"While these data are preliminary, we are delighted with the results from this first group of subjects to receive long-term treatment with roflumilast cream, which support our belief that roflumilast cream, unlike high potency steroids, can be used chronically," said [Frank Watanabe](#), Arcutis' President and Chief Executive Officer. "While we are still awaiting the full results from this study, we are encouraged by these early indications that the long-term efficacy and tolerability seem to be consistent with the results seen in the parent study. For far too long, patients and their dermatologists have been forced to make trade-offs in efficacy, safety, and tolerability due to the significant shortcomings of existing topical treatments for psoriasis. We continue to believe that topical roflumilast has the potential to offer an ideal combination of efficacy comparable to a high potency steroid, the ability to use the drug chronically in any anatomical area, and a favorable safety and tolerability profile. We are hopeful that topical roflumilast, if approved, will help dermatologists and their patients to overcome these difficult clinical compromises."

The roflumilast cream long-term safety study is a Phase 2, multi-center, open label study of the long-term safety and efficacy of roflumilast cream 0.3% in adult subjects with chronic plaque psoriasis involving up to 25% total body surface area (BSA), evaluated in two ongoing cohorts: subjects who completed the ARQ-151-201 Phase 2b, randomized, controlled trial; and previously untreated subjects. The subjects apply roflumilast cream 0.3% once daily for 52 weeks at home. Some subjects who entered this long-term study after completing the parent Phase 2b study will therefore have received up to 64 weeks of total treatment with topical roflumilast (12 weeks in the parent Phase 2b study and 52 weeks in the long-term safety study). Periodic clinic visits include assessments for clinical safety, application site reactions, and disease improvement or progression. The primary outcome measures of the study are the occurrence of treatment emergent adverse events and the occurrence of serious adverse events. Full results from this study are expected in the first quarter of 2021.

Roflumilast cream is a once-daily 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 systemic 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 Psoriasis

Psoriasis is a common, non-contagious, immune disease that affects approximately 8.6 million patients in the United States and requires chronic treatment. About 90% of psoriasis cases are 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 the plaques 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 <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 of roflumilast cream to address the unmet needs in the topical treatment of psoriasis; the potential safety and efficacy of roflumilast cream; and the timing of clinical data readouts. 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 May 12, 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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