



## 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 cream demonstrated favorable safety and tolerability over 52 to 64 weeks of treatment
- At 52 to 64 weeks of treatment, over one-third of subjects demonstrated IGA Success and 45% of subjects had attained an IGA of clear or almost clear
- Data further support the potential of roflumilast cream as a novel, once-daily, chronic topical treatment for plaque psoriasis, including intertriginous psoriasis
- Pivotal Phase 3 data in plaque psoriasis are anticipated in first quarter of 2021

WESTLAKE VILLAGE, Calif., Dec. 01, 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 positive results for the [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](#).

The long-term safety study enrolled 332 patients, including one cohort (Cohort 1) of patients who elected to continue open-label treatment (n=230) following their participation in the double-blind, randomized Phase 2b study of roflumilast cream in plaque psoriasis, the results from which were published in the [New England Journal of Medicine](#), and second cohort (Cohort 2) of treatment naïve patients (n=102). The maximum duration of treatment ranged from 52 weeks for naïve patients and those treated with vehicle in the randomized Phase 2b study, to 64 weeks for those treated with roflumilast cream for 12 weeks in the randomized Phase 2b study. In this open-label study, roflumilast cream 0.3% applied once daily for up to 52 weeks demonstrated favorable safety and tolerability over the long-term treatment period, consistent with what was seen in the randomized Phase 2b study, with only 3.6% of patients experiencing a treatment-related adverse event during 52 weeks of treatment. At week 52 of the long-term safety study, 44.8% of all subjects attained an Investigator Global Assessment (IGA) of clear or almost clear, with 34.8% of subjects in Cohort 1 and 39.5% of subjects in Cohort 2 achieving IGA Success, defined as a score of clear or almost clear plus a two-grade improvement from baseline. Additionally, of the subjects in the 12 week randomized Phase 2b study who were treated with roflumilast cream 0.3%, and who attained an IGA of clear or almost clear at 12 weeks in the first study, then continued on treatment in the long-term safety study, 66.7% had an IGA of clear or almost clear at the end of 64 weeks of treatment or their last visit. Of the 332 subjects in this study, 73.5% completed the full 52 weeks of open label treatment, with only 3.9% of subjects discontinuing the study due to an adverse event and less than 1% of subjects discontinuing due to lack of efficacy. There were no treatment related serious adverse events reported.

"We are delighted with the results from this study of patients receiving long-term treatment with roflumilast cream, which support our belief that roflumilast cream, unlike high potency steroids, can be used chronically," said [Patrick Burnett](#), M.D., Ph.D., FAAD, Arcutis' Chief Medical Officer. "We are encouraged that the efficacy and tolerability seen in this long-term study are consistent with the results seen in the double-blind Phase 2b study, and the unusually high proportion of patients who completed the full 52 weeks of treatment bodes well for real-world patient persistence. We believe there is a significant unmet need from patients and their dermatologists, who for too long have been forced to make trade-offs between efficacy, safety, and tolerability due to the significant shortcomings of existing topical treatments for psoriasis. Based on the strength of our clinical data to date, we 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. We look forward to the results from the ongoing DERMIS-1 and DERMIS-2 Phase 3 clinical trials of ARQ-151 in plaque psoriasis, which are anticipated in the first quarter of next year."

The roflumilast cream long-term safety study was 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 cohorts: subjects who completed the ARQ-151-201 Phase 2b, randomized, controlled trial; and previously untreated subjects. Subjects applied roflumilast cream 0.3% once daily for 52 weeks at home. Approximately half (164 out of 332) of the subjects entered this long-term study after completing treatment with roflumilast cream 0.3% or 0.15% in the randomized Phase 2b study and therefore received up to 64 weeks of total treatment with topical roflumilast (12 weeks in the randomized Phase 2b study and 52 weeks in the long-term safety study). Periodic clinic visits included assessments for clinical safety, application site reactions, and disease improvement or progression. The primary outcome measures of this long-term safety study were the occurrence of treatment emergent adverse events and the occurrence of serious adverse events.

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 [www.arcutis.com](http://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 November 5, 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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