



The New England Journal of Medicine Publishes Results from Positive Phase 2b Trial of Arcutis' ARQ-151 (Topical Roflumilast Cream) for the Treatment of Chronic Plaque Psoriasis

July 15, 2020

- Data demonstrate potential “Best in Class” topical PDE4 inhibitor roflumilast significantly improves chronic plaque psoriasis
- Phase 3 topline data anticipated first half of 2021

WESTLAKE VILLAGE, Calif., July 15, 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, announced today that [The New England Journal of Medicine](#) has published positive results from a Phase 2b trial of its investigational drug [topical roflumilast cream](#) for the treatment of chronic plaque psoriasis. The article has been published in the July 16 issue of the journal. These results demonstrate that ARQ-151 (roflumilast cream) administered once daily was superior to a matching vehicle in treating psoriasis, as measured by a rating of clear or almost clear at week six on the Investigator Global Assessment (IGA) scale.

“Plaque psoriasis imposes a significant burden on patients, and is often associated with poor quality of life. Effectively treating psoriasis with topical therapies, which the vast majority of patients receive, is especially challenging due to side effects, tolerability or efficacy of existing topical treatments,” said Mark Lebwohl, MD, Waldman Professor and Chair of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai, and the lead author of the publication. “These data demonstrate that once-daily topical roflumilast cream was well-tolerated and achieved early and significant improvements in psoriasis signs and symptoms, including in the hard-to-treat intertriginous areas such as the armpit or groin, where two skin surfaces touch.”

Roflumilast cream (ARQ-151) is a once-daily, highly potent, selective phosphodiesterase-4 (PDE-4) inhibitor being developed for chronic plaque psoriasis. Arcutis is currently conducting a Phase 3 clinical program with topical roflumilast cream, including two ongoing Phase 3 clinical trials (DERMIS-1 and -2). The company anticipates topline data from the Phase 3 studies in the first half of 2021.

“The positive results from this study are particularly encouraging for patients who need new and better options to treat this chronic skin disease. Roflumilast once-daily cream demonstrated significant improvements in psoriasis signs and symptoms,” said Dr. Linda Stein Gold, Director of Dermatology Clinical Research and Division Head of Dermatology at the Henry Ford Hospital in Detroit, Michigan, and an investigator in the study. “The results demonstrated statistical significance in an investigator determination of clear or almost clear as well as improvement in patient-reported measures, such as itch and burden of disease. Additionally, notable efficacy was demonstrated as early as within two weeks and topical roflumilast cream was well-tolerated throughout the study.”

In the Phase 2b, double-blinded trial, a total of 331 adults with plaque psoriasis were randomly assigned in a 1:1:1 ratio to receive topical treatment with roflumilast cream 0.3%, 0.15%, or matching vehicle applied once daily for 12 weeks. 109 patients were treated with roflumilast cream 0.3%, 113 with 0.15% cream, and 109 with the vehicle. The primary efficacy outcome was Investigator Global Assessment (IGA, a 5-item scale assessing plaque thickening, scaling, and erythema, ranging from 0-clear to 4-severe) of clear or almost clear at week 6. Secondary outcomes included clear or almost clear plus a 2-grade improvement (IGA Success), IGA Success on an Intertriginous IGA, and change in Psoriasis Area and Severity Index (PASI).

The primary efficacy endpoint of an IGA score indicating clear or almost clear at Week 6 was 28 percent, 23 percent and 8 percent for roflumilast 0.3%, roflumilast 0.15% and vehicle ($p < 0.001$ and $p = 0.004$, vs vehicle for roflumilast 0.3% and 0.15%, respectively). The secondary endpoint of an IGA score indicating clear or almost clear *plus* 2-grade improvement from baseline demonstrated that patients treated with both roflumilast doses showed separation from vehicle from Week 6 through Week 12, with Week 12 rates of 31% and 27% for roflumilast 0.3% and 0.15%, respectively, vs 14% for vehicle. Among the approximately 15% of patients with baseline intertriginous psoriasis of at least mild severity, 14 of 15 (93%) patients treated with roflumilast 0.3% had an Intertriginous-IGA score of 0 (clear) at Week 12 compared with 3 of 17 (18%) patients in the vehicle group. At Week 12, PASI-75 response rates (improvements in PASI from baseline of at least 75%) were 34% for roflumilast 0.3% vs 16% for vehicle. Application site reactions were less common in the roflumilast cream arms than the vehicle arm. Adverse events were reported in 39 percent, 27 percent and 30 percent of patients receiving roflumilast 0.3%, 0.15%, and vehicle, respectively. Ninety-seven percent of adverse events were rated mild or moderate in severity. In addition, 94 percent of patients completed the trial in the roflumilast 0.3% arm.

“The results from this Phase 2b study provide further evidence of the potential of roflumilast cream as a once-daily treatment for patients with plaque psoriasis who currently lack suitable treatment options,” said [Frank Watanabe](#), Arcutis' President and Chief Executive Officer. “We are pleased to share these results, which suggest topical roflumilast was well tolerated and efficacious, with the broader scientific community in such a prestigious journal.”

Please refer to the paper, “Trial of Roflumilast Cream for Chronic Plaque Psoriasis” for the full description of the design and results of this study.

About ARQ-151 (Topical Roflumilast Cream)

Topical roflumilast cream is a once-daily, topical cream formulation containing roflumilast, a PDE4 inhibitor, that Arcutis is developing to treat plaque psoriasis, including intertriginous psoriasis, and atopic dermatitis. PDE4 is an intracellular enzyme that regulates pro-inflammatory and anti-inflammatory cytokine production and cell proliferation. Roflumilast was approved by the FDA for systemic treatment to reduce risk of exacerbation of chronic obstructive pulmonary disease (COPD) in 2011, and has shown greater potency (25 - 300 fold) than other two FDA-approved PDE4 inhibitors used in dermatology.

About Psoriasis

Psoriasis is an immune disease that occurs in about two percent of adults in western countries. About 90% of psoriasis cases is plaque psoriasis, which is characterized by “plaques”, or 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 areas (where two skin areas may touch or rub together).

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](#).

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Phase 2B Trial of Roflumilast Cream (ARQ-151) for the Treatment of Chronic Plaque Psoriasis: <http://ml.globenewswire.com/Resource/Download/6a25f0f8-31fc-439d-bcf8-13f6e9514e0b>