Data demonstrate potential “Best in Class” topical PDE4 inhibitor roflumilast significantly improves signs and symptoms of chronic plaque psoriasis

Phase 3 topline data anticipated first half of 2021

The 1/2a study assessed the safety and efficacy of once-daily roflumilast cream 0.5% and 0.15% in patients with chronic plaque psoriasis. The study enrolled a single-dose, open-label Phase 1 cohort (0.5% cream applied to 25 cm² psoriatic plaques), and a 28-day, double-blinded Phase 2a cohort (1:1:1 randomization to roflumilast cream 0.5%, 0.15%, or vehicle). Patients had chronic plaque psoriasis of > 6 months’ duration with ≤5% body surface area involvement. Outcomes included safety (adverse events) and efficacy (percentage change in the product of Target Plaque Severity Score [TPSS] and Target Plaque Area [TPA]) at week 4.

For Cohorts 1 (n=8) and 2 (n=89), adverse events (all mild/moderate; none serious or severe) were similar between active arms and vehicle. Treatment-related events were confined to the application site, with no difference between active and vehicle. No patient discontinued treatment due to adverse events. The primary efficacy endpoint was met for both roflumilast cream doses: TPSS×TPA improvement at week 4 was statistically significant for roflumilast 0.5% (P=0.0007) and 0.15% (P=0.0011) versus vehicle; significance was reached as early as 2 weeks. For both roflumilast cream doses, 66% to 67% improvement from baseline was observed at week 4, without reaching a plateau, versus 38% improvement for vehicle.

“The results from this Phase 1/2a 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, and who often have to settle for trade-offs in drug efficacy, safety, and tolerability,” said Frank Watanabe, Arcutis’ President and Chief Executive Officer. “We believe that topical roflumilast has the potential to deliver the efficacy that enables meaningful symptomatic improvement and a safety and tolerability profile that supports chronic use and the ability to use in all body areas.”

Please refer to the paper, “Roflumilast Cream Improves Signs and Symptoms of Plaque Psoriasis: Results from a Phase 1/2a Randomized, Controlled Study” 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, 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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