Arcutis Announces Top Line Results for Phase 2 Proof-of-Concept Clinical Trial Evaluating ARQ-151 as a Potential Topical Treatment for Atopic Dermatitis

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- Consistent evidence of symptomatic improvement across endpoints and favorable tolerability
- Higher dose demonstrated trend towards significance on primary endpoint
- Both doses statistically superior to vehicle on key secondary endpoints
- Company plans to advance ARQ-151 development in atopic dermatitis, with Phase 2b initiation anticipated in 2H 2020

Westlake Village, CA, December 16, 2019 – Arcutis Biotherapeutics, Inc., a privately held 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 top line results for a Phase 2 proof-of-concept study evaluating ARQ-151 as a potential topical treatment for atopic dermatitis (AD). ARQ-151 is a once daily topical cream formulation of roflumilast, a highly potent and selective Phosphodiesterase type 4 inhibitor (PDE4), which the Company is developing for plaque psoriasis and AD.

The ARQ-151-212 study was a Phase 2 multi-center, double blind, vehicle-controlled proof-of-concept study, in which 136 adolescents (ages 12 years and above) and adults with mild to moderate AD involving between 1.5% and 35% body surface area (BSA) were randomized to receive once daily topical applications for 4 weeks of: (1) ARQ-151 0.15% cream, or (2) ARQ-151 0.05% cream, or (3) vehicle. The study assessed the safety, tolerability, pharmacokinetics (PK) and efficacy of the two dose levels of ARQ-151.

On the study's primary endpoint, the mean reduction in the Eczema Area and Severity Index (EASI) Total Score after 4 weeks of once-daily treatment, neither dose reached statistical significance versus vehicle, although ARQ-151 0.15% showed a trend towards significance, with a mean improvement of 6.4 in patients treated with ARQ-151 0.15% compared to 4.8 in patients treated with vehicle ($p = 0.097$). On the secondary endpoint of mean percent change from baseline on EASI, ARQ-151 0.15% demonstrated a statistically significant improvement versus vehicle (72.3% versus 55.8%, $p = 0.049$). Efficacy was also observed at both doses as measured by EASI-75 (ARQ-151 0.05%: 59.1% versus

vehicle: 31.1%, p = 0.009 and ARQ-151 0.05%: 52.3% versus vehicle: 31.1%, p = 0.045). On the Validated Investigator Global Assessment – Atopic Dermatitis (vIGA-AD), ARQ-151 0.15% also demonstrated a statistically significant improvement versus vehicle in the percentage of patients achieving clear or almost clear (ARQ-151 0.15%: 52.3% versus vehicle: 31.1%, p = 0.040).

In this study, both doses of ARQ-151 were well-tolerated. 95% of subjects on active treatment completed the full study. The incidence of treatment-related Treatment Emergent Adverse Events (TEAEs) and application site reactions were low (< 5%) and similar between active treatment and vehicle. TEAEs were mild to moderate in severity. Among subjects receiving ARQ-151, there was only one Serious Adverse Event (SAE), which was unrelated to treatment, and only one discontinuation due to a TEAE.

Frank Watanabe, Arcutis' Chief Executive Officer, commented: "We are very encouraged by the results from this small, proof-of-concept study. The consistent separation from vehicle on multiple endpoints, and the magnitude of improvement in atopic dermatitis demonstrated in this study further reinforce our belief that ARQ-151 has the potential to be an effective atopic dermatitis therapy. As important, both doses evaluated showed a very favorable tolerability profile, which is particularly important given the majority of atopic dermatitis patients are children. Based on the strength of these results, we plan to pursue further development of ARQ-151 in atopic dermatitis, with a Phase 2b study planned for the second half of 2020."

About ARQ-151

ARQ-151 is a topical cream formulation containing roflumilast, a PDE4 inhibitor, that the Company is developing to treat plaque psoriasis, including intertriginous psoriasis, and atopic dermatitis. PDE4 is an intracellular enzyme that regulates the production of pro-inflammatory and anti-inflammatory cytokines and cell proliferation. Roflumilast is a potent PDE4 inhibitor that was approved by the U.S. Food and Drug Administration (FDA) for systemic treatment to reduce risk of exacerbation of chronic

obstructive pulmonary disease (COPD) in 2011, and has shown greater potency based on IC50 values (a non-clinical measure of a drug's potency) than other PDE4 inhibitors.

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 is paramount.

About Arcutis - Bioscience, applied to the skin.

Arcutis 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. Arcutis exploits recent innovations in inflammation and immunology to develop potential best-in-class therapies against validated biological targets, leveraging our deep development, formulation and commercialization expertise to bring to market novel dermatology treatments, while maximizing our probability of technical success and financial resources. Arcutis is currently developing three novel products (ARQ-151, ARQ-154 and ARQ-252) for multiple indications including psoriasis, atopic dermatitis, seborrheic dermatitis and eczema. For more information, please visit www.arcutis.com or follow Arcutis on LinkedIn.

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