**Arcutis Biotherapeutics Announces Positive End-of-Phase 2 Meeting with FDA and Planned Initiation of Phase 3 Program for ARQ-151 for Plaque Psoriasis**

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**Arcutis Also Announces Enrollment of Last Patient in 52-Week Long-term Safety Study of ARQ-151 Cream as a Potential Topical Treatment for Plaque Psoriasis**

**Westlake Village, CA, Oct. 24, 2019** – Arcutis Biotherapeutics, Inc. (Arcutis), a privately held clinical-stage biopharmaceutical company focused on developing and commercializing treatments for unmet needs in immune-mediated dermatological diseases and conditions, or immuno-dermatology, today announced plans to initiate its Phase 3 program of ARQ-151 as a potential topical treatment for plaque psoriasis following its End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA). The Company anticipates initiating a Phase 3 clinical trial in the first half of 2020.

Frank Watanabe, Arcutis' President and Chief Executive Officer, commented: "We appreciate the collaborative interaction with the FDA to reach agreement on the key elements of our Phase 3 program that we intend to use to support the submission of a New Drug Application for ARQ-151 for plaque psoriasis. Based on our clinical data to date, we believe ARQ-151 has the potential to be both a best-in-class topical PDE4 inhibitor and the only topical PDE4 inhibitor approved for plaque psoriasis. We look forward to starting our Phase 3 program in the first half of next year."

The Company also announced that it has completed enrollment of a 52-week Phase 2 long-term safety study of ARQ-151 in plaque psoriasis. Topline results are expected in the first half of 2021. The Company expects this study to supply the 12-month safety data required for regulatory submissions. In the previous Phase 2b trial in plaque psoriasis, both tested doses of ARQ-151 were well tolerated and demonstrated rapid onset of effect with statistically significant superiority over vehicle. ARQ-151 is a topical cream formulation of roflumilast, a highly potent and selective Phosphodiesterase type 4 (PDE4) inhibitor, which the Company is developing for once-a-day application to treat plaque psoriasis and atopic dermatitis.

Howard Welgus, Arcutis' Chief Medical Officer, commented: "Because psoriasis is a chronic disease, it is critical to understand the efficacy, safety and tolerability of any new psoriasis treatment over an extended period. Thus, this long-term safety study is important to our understanding of ARQ-151's potential to address the unmet needs in topical treatment of psoriasis. Furthermore, this strategic clinical development approach to generating long-term safety data allows our Phase 3 studies to be of shorter duration."

The ARQ-151-202 study is a Phase 2, multi-center, open label study of the long-term safety of ARQ-151 0.3% cream in adult subjects with chronic plaque psoriasis involving up to 25% total body surface area (BSA), evaluated in two cohorts: 231 patients who have completed the ARQ-151-201 Phase 2b, randomized, controlled trial; and 102 previously untreated subjects. The qualifying subjects will apply ARQ-151 0.3% cream once daily for 52 weeks at home. Periodic clinic visits will 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.

**About ARQ-151**

ARQ-151 is a 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 the production of pro-inflammatory and anti-inflammatory cytokines and cell proliferation. Roflumilast is a potent PDE4 inhibitor that 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 based on IC50 values (a non-clinical measure of a drug's potency) than other PDE4 inhibitors.

**About Psoriasis**

Psoriasis is a common, non-contagious, immune disease that affects approximately 8.6 million patients in the United States. About 90% of psoriasis cases are 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 regions such as the groin, axillae and inframammary areas.

**About Arcutis -** Bioscience, applied to the skin.

Arcutis is a clinical-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 two novel compounds (ARQ-151 and ARQ-252) for multiple indications including psoriasis, atopic dermatitis and eczema. For more information, please visit www.arcutis.com or follow the Company on LinkedIn.

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