



Arcutis, Inc. Announces Positive Top Line Results for Phase 2b Clinical Trial Evaluating ARQ-151 as a Potential Topical Treatment for Plaque Psoriasis

- Both tested doses of ARQ-151 demonstrated statistically significant superiority over vehicle
 - Favorable safety and tolerability in this patient population
 - ARQ-151 potential “Best in Class” topical PDE4 inhibitor
 - Phase 3 initiation anticipated in 1Q 2020

Westlake Village, CA, July 22, 2019 – [Arcutis, Inc.](#), a privately held immuno-dermatology drug development company addressing significant unmet needs in dermatology, today announced positive top line results for its [Phase 2b study](#) evaluating [ARQ-151](#) as a potential topical treatment for [plaque psoriasis](#).

On the study’s primary endpoint, ARQ-151 produced statistically significant reductions compared to vehicle (ARQ-151 0.3%: $p < 0.001$, ARQ-151 0.15%: $p = 0.004$) in the signs of plaque psoriasis, as measured by an Investigator Global Assessment (IGA) score of “clear” or “almost clear”, after 6 weeks of once-daily treatment, and was very well-tolerated with minimal adverse events in the study population. On one of the study’s secondary endpoints (the probable registrational endpoint for planned Phase 3 studies), ARQ-151 0.3% had an ‘IGA Success’ (clear/almost clear + 2-grade improvement from baseline) rate of 32.2%, and ARQ-151 0.15% had an ‘IGA Success’ rate of 24.5% compared to a vehicle ‘IGA Success’ rate of 9.8% (ARQ-151 0.3%: $p < 0.001$, ARQ-151 0.15%: $p = 0.005$) after 8 weeks of once-daily application. ARQ-151 0.3% also separated statistically from vehicle on all secondary endpoints, including reductions in Intertriginous IGA (I-IGA), Psoriasis Area Severity Index (PASI), reductions in itch as measured by the Worst Itch-Numerical Rating Scale (WI-NRS), and patient perceptions of symptoms as measured by the Psoriasis Symptoms Diary (PSD), and ARQ-151 0.15% separated statistically from vehicle on all secondary endpoints except for I-IGA.

[Frank Watanabe](#), Arcutis’ President and Chief Executive Officer, commented: “We are delighted with the strength of this Phase 2b data, which confirms the positive results we saw in our Phase 2a study. This data reinforces our belief that ARQ-151 is uniquely suited to address the unmet needs in the topical treatment of psoriasis, offering an ideal combination of efficacy comparable to a high potency



steroid, the ability to use the drug chronically in any anatomical area, and a very favorable safety and tolerability profile. We look forward to presenting the full results of this study at an upcoming scientific meeting, and to advancing the development of this potential new psoriasis treatment with the initiation of our Phase 3 development program in the first quarter of 2020.”

The Phase 2b study was a randomized, parallel group, double-blind, vehicle-controlled, multi-national, multi-center study in which ARQ-151 0.3% cream or ARQ-151 0.15% cream or vehicle cream were applied once daily for 12 weeks to subjects with chronic plaque psoriasis involving between 2% and 20% body surface area. The study enrolled 332 patients. The IGA scale is a visual assessment that consists of a score ranging from 0 (clear) to 4 (severe). Skin rated a 4 is bright red in color with marked plaque elevation and is dominated by thick, non-tenacious scale. For a treatment to be considered successful, from a regulatory standpoint, the affected area must receive a score of 0 or 1 and experience a two-point improvement from baseline.

In this Phase 2b study, ARQ-151 was very well-tolerated in this population. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar between active treatment and vehicle, with nearly all TEAEs mild to moderate in severity. Among subjects receiving ARQ-151, there was only one discontinuation due to a TEAE (< 1% of subjects) and two Serious Adverse Events (neither related to drug).

About ARQ-151

ARQ-151 is a topical cream formulation of a highly potent and selective PDE4 inhibitor (roflumilast) that has been approved globally for the systemic treatment of COPD since 2011 and that is many-fold more potent than any other disclosed PDE4 inhibitor. Phosphodiesterase type 4 (PDE4) is an intracellular enzyme that increases the production of proinflammatory mediators, and decreases the production of anti-inflammatory mediators, and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and chronic obstructive pulmonary disease (COPD). PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the U.S. Food



and Drug Administration for the topical treatment of atopic dermatitis and the systemic treatment of plaque psoriasis.

About Psoriasis

Psoriasis is a common, non-contagious, immune disease that affects more than 125 million people worldwide (approximately 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 is a clinical-stage biopharmaceutical company focused on developing and commercializing drugs that address significant unmet medical needs in immuno-dermatology. Arcutis exploits recent innovations in inflammation and immunology to develop best-in-class molecules against biologically validated targets, leveraging our industry-leading development expertise to bring to market novel dermatology treatments in less time, at lower cost and with lower risk than other approaches. Arcutis is currently developing two novel compounds (ARQ-151 and ARQ-250) 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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