



Arcutis Announces Enrollment of First Patients in Two Pivotal Phase 3 Clinical Trials Evaluating ARQ-151 as a Potential Once Daily Topical Treatment for Plaque Psoriasis

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- ARQ-151 potential "Best in Class" topical PDE4 inhibitor
- Plaque psoriasis affects approximately 8.6 million patients in the U.S.
- Phase 3 trials topline data anticipated first half 2021

WESTLAKE VILLAGE, CA / ACCESSWIRE / January 8, 2020 / [Arcutis Biotherapeutics, Inc.](#) (Arcutis), 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 enrollment of the first patients in both of the Company's pivotal Phase 3 clinical trials evaluating [ARQ-151](#) as a potential topical treatment for [plaque psoriasis](#).



[Frank Watanabe](#), Arcutis' President and Chief Executive Officer, commented: "We are very excited to be enrolling the pivotal trials of ARQ-151 in plaque psoriasis. Based on our clinical data to date, we believe ARQ-151 has the potential to be both the best-in-class topical PDE4 inhibitor and the only topical PDE4 inhibitor approved for plaque psoriasis. Our Phase 3 clinical trials build on our prior clinical development in which ARQ-151 demonstrated statistically significant improvements of psoriasis symptoms and a favorable safety and tolerability profile in two separate Phase 2 studies. With these Phase 3 clinical trials, we hope to advance a potential new once daily treatment for patients who currently do not have adequate treatment options."

The "Trials of PDE4 inhibition with Roflumilast for the Management of plaque Psoriasis" One and Two (or DERMIS-1 and DERMIS-2) are identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multi-national, multi-center studies in which ARQ-151 0.3% cream or vehicle cream are applied once daily for 8 weeks to subjects aged 12 and above with mild, moderate or severe chronic plaque psoriasis involving between 2% and 20% body surface area. The studies will each enroll approximately 400 patients. The primary endpoint of the studies is Investigator Global Assessment (IGA) Success, defined as an IGA score of clear or almost clear and at least a 2-grade improvement from baseline at week 8 on the IGA score. Multiple secondary endpoints will also be evaluated, including Intertriginous IGA (I-IGA) Success, and improvements in Psoriasis Area Severity Index

(PASI), 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). The Company anticipates topline data from the Phase 3 studies in the first half of 2021.

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 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 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-mediated skin disease that affects approximately 8.6 million patients in the United States. About 90% of patients develop plaque psoriasis, which is characterized by 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 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 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 compounds (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 the Company on [LinkedIn](#).

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