



Arcutis Announces ARQ-154 Program for Scalp Psoriasis and Enrollment of First Patient in Phase 2b Clinical Trial

- ARQ-154 potential “Best in Class” topical PDE4 inhibitor in foam formulation
- Scalp psoriasis affects over 2.5 million U.S. patients
- Phase 2b trial topline data anticipated fourth quarter 2020 or first quarter 2021

Westlake Village, CA, January 21, 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 provided details on the [ARQ-154](#) clinical development program for scalp psoriasis. ARQ-154 is a once-daily topical foam formulation of a highly potent and selective phosphodiesterase type 4 inhibitor (PDE4 inhibitor) that the Company is developing particularly to treat inflammatory dermatoses in hair-bearing areas of the body such as the scalp. The Company also announced that it has enrolled the first patient in a [Phase 2b clinical trial](#) evaluating the compound as a potential treatment for scalp psoriasis.

[Frank Watanabe](#), Arcutis’ President and Chief Executive Officer, commented: “Nearly half of the estimated 8.6 million Americans with psoriasis have scalp involvement. Like other patients with psoriasis, scalp psoriasis sufferers need novel therapies that offer good efficacy, the ability to use the drug chronically, and an excellent safety and tolerability profile. Patients with scalp psoriasis also need therapies that are safe to use near the eyes, in a formulation that effectively delivers drug to affected areas of the scalp without significantly affecting the appearance of their hair. We believe ARQ-154 may provide a new treatment option for physicians and patients, with the potential to show significant symptomatic improvement, while maintaining a low risk of toxicity or side effects, and suitability for chronic use, all in a foam formulation that is convenient to use both on hair-bearing areas as well as other areas of the body.”



ARQ-154 is a topical foam formulation of a highly potent and selective PDE4 inhibitor (roflumilast). Roflumilast has been approved by the U.S. Food and Drug Administration (FDA) for systemic treatment to reduce the risk of exacerbations of chronic obstructive pulmonary disease (COPD) since 2011. Roflumilast has shown greater potency based on IC50 values (a non-clinical measure of a drug's potency) than any other disclosed PDE4 inhibitor. PDE4 is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators and has been implicated in a wide range of inflammatory diseases including psoriasis, eczema, and COPD. PDE4 is an established target in dermatology, and other PDE4 inhibitors have been approved by the FDA for the topical treatment of atopic dermatitis or the systemic treatment of plaque psoriasis.

Arcutis believes ARQ-154 has significant potential as a scalp psoriasis treatment. ARQ-154 is nearly identical to ARQ-151, Arcutis' topical cream PDE4 inhibitor that has demonstrated statistically significant improvements of psoriasis symptoms and a favorable tolerability profile in two separate Phase 2 studies. Psoriasis plaques on the scalp are identical to plaques elsewhere on the body, so the ARQ-151 psoriasis results should be highly predictive.

The Phase 2b trial is an 8-week, multi-center, multi-national, double blind, vehicle-controlled, study of the safety and efficacy of ARQ-154 0.3% topical foam administered once-daily in approximately 300 adult and adolescent patients with plaque psoriasis that includes plaques on the scalp. The primary endpoints of the trial are achievement of an Investigator Global Assessment Scale score of 'clear' or 'almost clear' plus a 2-grade improvement from baseline on the scalp (S-IGA), and separately, the attainment of 'clear' or 'almost clear' plus a 2-grade improvement on the body (B-IGA), both at week 8. Multiple secondary endpoints will also be evaluated. The Company anticipates topline data from the trial in the fourth quarter of 2020 or the first quarter of 2021.



About Scalp Psoriasis

Scalp psoriasis is a manifestation of plaque psoriasis characterized by raised, red areas of skin (“plaques”) covered with a silver or white layer of dead skin cells that occurs in the hair-bearing area of the scalp and sometimes extending to the forehead, back of the neck, or behind or inside the ears. Patients with scalp psoriasis commonly have plaques on other areas of the body as well. Nearly half of the estimated 8.6 million Americans with psoriasis have involvement of the scalp. Scalp psoriasis plaques are identical to psoriatic plaques on other areas of the, however topical treatment of scalp plaques is complicated by the difficulty of delivering topical drugs under the hair. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area.

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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