Arcutis Submits Supplemental New Drug Application for ZORYVE® (roflumilast) Cream 0.3% for Expanded Indication for the Treatment of Plaque Psoriasis in Children Down to 2 Years of Age

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- Regulatory submission for the expanded indication is supported by data from two recently completed 4-week Maximal Usage Systemic Exposure (MUSE) studies in children ages 2 to 11 years with plaque psoriasis
- If approved, ZORYVE would be the first steroid-free topical phosphodiesterase-4 (PDE4) inhibitor for children with plaque psoriasis
- ZORYVE has been shown to be safe and very well tolerated, with minimal local site reactions

WESTLAKE VILLAGE, Calif., Dec. 19, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the submission of a supplemental new drug application (sNDA) to the U.S. Food and Drug Administration (FDA) for the expanded indication of ZORYVE (roflumilast) cream 0.3% for the treatment of plaque psoriasis in children ages 2 to 11. As with adults and adolescents, plaque psoriasis is the most common form of psoriasis in children 2 to 11 years of age, with very similar clinical features.

ZORYVE was approved by the FDA in July 2022 for the topical treatment of plaque psoriasis in adults and adolescents 12 years of age and older. ZORYVE is a steroid-free, topical PDE4 inhibitor which effectively clears plaque psoriasis in both hard-to-treat areas such as knees and elbows, as well as sensitive areas such as the face, intertriginous areas, and genitalia.

“Safety and tolerability are critically important in the treatment of children, and today young children lack treatment options for plaque psoriasis. This submission is an exciting step in our efforts to expand the availability of an effective, steroid-free treatment for children with plaque psoriasis,” said Patrick Burnett, MD, PhD, FAAD, Chief Medical Officer at Arcutis. “ZORYVE is the first PDE4 approved for the treatment of psoriasis and, if approved by the FDA with the new data, dermatology clinicians will be able to treat patients down to 2 years of age.”

“ZORYVE demonstrated a favorable safety and tolerability profile in this pediatric population, with minimal local site reactions. ZORYVE, with our proprietary HydroARQ Technology™, is a non-greasy, moisturizing cream that spreads easily and is aesthetically pleasing to patients, and most importantly does not include sensitizing excipients or irritants such as propylene glycol,” added Frank Watanabe, President and CEO at Arcutis.

The submission is based on data from two recently completed 4-week MUSE studies (NCT04655313 ; NCT04746911) in children aged 2 to 11 years with plaque psoriasis. Pharmacokinetic, safety, tolerability, and efficacy data from these two studies are consistent with data from the DERMIS-1 and DERMIS-2 pivotal Phase 3 trials. Arcutis worked with the FDA on the design of the MUSE studies, which are intended to fulfill FDA post-marketing requirements for ZORYVE.

About ZORYVE®
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION
The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full Prescribing Information.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is an early commercial-stage medical dermatology company that champions meaningful innovation to address the urgent needs of individuals living with immune-mediated dermatological diseases and conditions. With a commitment to solving the most persistent patient challenges in dermatology, Arcutis has a growing portfolio that harnesses our unique dermatology development platform coupled with our dermatology expertise to build differentiated therapies against biologically validated targets. Arcutis’ dermatology development platform includes a robust pipeline with multiple clinical programs for a range of inflammatory dermatological conditions including scalp and body psoriasis, atopic dermatitis, seborrheic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

Forward-Looking Statements
Arcutis cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company’s current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding the potential for ZORYVE to simplify disease management for care of plaque psoriasis; the potential for roflumilast to gain an expanded approval for the treatment of children ages 2-11 years for plaque psoriasis; the potential of real-world use results of roflumilast cream, as well as the commercial launch of ZORYVE in plaque psoriasis. These statements are subject to substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in our business, reimbursement and access to our products, the impact of competition and other important factors discussed in the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as amended, as well as any subsequent filings

with the SEC. You should not place undue reliance on any forward-looking statements in this press release. We undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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