Arcutis Launches ZORYVE™ (Roflumilast) Cream 0.3% in the United States for Treatment of Plaque Psoriasis in Individuals Age 12 and Older

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- *Next-generation topical PDE4 inhibitor for adults and adolescents with plaque psoriasis now available in pharmacies nationwide*
- *Effective, safe, and very well-tolerated steroid-free cream that rapidly clear plaques and reduces itch*
- *Arcutis committed to ensuring affordable access through responsible pricing, Arcutis Cares™ and ZORYVE Direct™ patient access support program*

WESTLAKE VILLAGE, Calif., Aug. 10, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that ZORYVE (roflumilast) cream 0.3% for topical use is now available in the United States for the treatment of plaque psoriasis in people aged 12 and older. As the first and only topical phosphodiesterase-4 (PDE4) inhibitor approved for the treatment of plaque psoriasis, ZORYVE clears plaques and reduces itch rapidly in all affected areas of the body, including intertriginous areas (areas of skin-to-skin contact). Featuring HydroARQ Technology™, a patient-friendly formulation that absorbs quickly and spreads easily, ZORYVE is an effective, well-tolerated, once-daily steroid-free cream with no restrictions on duration of use.

“We are excited to make ZORYVE, our first commercial product, available as an innovative topical therapy to individuals in the United States who are currently living with plaque psoriasis. ZORYVE is the only topical treatment option to date that was specifically studied and demonstrated efficacy in treating intertriginous plaque psoriasis, as well as on all other areas of the body, including hard to treat areas like knees and elbows,” said Ken Lock, Chief Commercial Officer of Arcutis. “The availability of ZORYVE so quickly following approval is a reflection of the strength of Arcutis’ manufacturing and commercial operations.”

ZORYVE is now available via ZORYVE Direct pharmacies and will be available for ordering at pharmacies nationwide no later than August 15. ZORYVE Direct pharmacies are contracted pharmacy partners that help commercially insured individuals with plaque psoriasis get access to and start ZORYVE treatment quickly and easily as prescribed by their healthcare provider. Additionally, ZORYVE Direct pharmacies help patients navigate the payer process, lower the out-of-pocket cost for eligible patients, and offer programs that support staying on therapy.†.

Arcutis is committed to helping patients have access to product, including setting a responsible price, working with payers to help ensure broad high-quality formulary access, and providing a patient access support program, as well as a patient assistance program (PAP). The Arcutis Cares™ PAP – the first of its kind for a topical psoriasis treatment – will provide ZORYVE at no cost for financially eligible patients who are uninsured or underinsured.‡

“At Arcutis, we strongly believe that meaningful innovation must extend beyond product development, and include a commitment to ensuring our products are accessible to the individuals who need them. With this in mind, we are executing a responsible pricing and go-to-market strategy for ZORYVE as yet another way to deliver innovative solutions for those living with plaque psoriasis,” said Frank Watanabe, President and CEO of Arcutis.

On July 29, Arcutis announced that the FDA had approved ZORYVE for both adults and adolescents with plaque psoriasis. ZORYVE is available by prescription only. For more information about ZORYVE visit zoryve.com.

About ZORYVE (roflumilast) cream 0.3%

ZORYVE 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 a 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 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 psoriasis, atopic dermatitis, and seborrheic dermatitis. 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; as well as the commercial launch of ZORYVE in plaque psoriasis, including product availability and access. 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, conditions limiting our ability to access additional capital under our debt financing agreement, 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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† Uninsured patients and patients with government insurance are not eligible for the ZORYVE Direct savings program; Other terms and restrictions apply

‡ Subject to financial eligibility requirements. Other terms and restrictions apply