FDA Approves Arcutis' ZORYVE™ (Roflumilast) Cream 0.3% For the Treatment of Plaque Psoriasis in Individuals Age 12 and Older

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- *First and only topical PDE4 inhibitor approved for the treatment of plaque psoriasis, including intertriginous psoriasis*
- *Approved for once-daily treatment in mild, moderate, and severe plaque psoriasis with no limitations on duration of use*
- *Established efficacy – provides rapid clearance of plaques and reduction of itch in all affected areas of the body*
- *Safe and very well-tolerated, steroid-free cream with minimal application site reactions*
- *Commercial product expected to be available by mid-August*
- *Management will host conference call on Monday, August 1 at 8:30 a.m. EDT*
- *Arcutis expects to draw an additional $125 million from the Company's debt facility with SLR Capital Partners*

WESTLAKE VILLAGE, Calif., July 29, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, announced today that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for ZORYVE (roflumilast) cream 0.3% for the treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age or older. The first and only topical phosphodiesterase-4 (PDE4) inhibitor approved for the treatment of plaque psoriasis, ZORYVE provides rapid clearance of psoriasis plaques and reduces itch in all affected areas of the body. ZORYVE — a once-daily, steroid-free cream in a safe and well tolerated, patient-friendly formulation — is uniquely formulated to simplify disease management for people living with plaque psoriasis.

"Today Arcutis has reached a major milestone, with our ability to offer this next generation topical PDE4 inhibitor to both adults and adolescents with plaque psoriasis. ZORYVE's combination of efficacy, safety, and tolerability, coupled with our proprietary HydroARQ Technology formulation, is designed to fit into patients' everyday lives with no restrictions on duration of use," said Frank Watanabe, President and CEO of Arcutis. "Additionally, ZORYVE has been shown to rapidly clear plaques and reduce itch across all areas of the body. ZORYVE is the only topical for which data focused on the treatment of intertriginous plaques — a common area affected by plaque psoriasis — have been specifically generated. This FDA approval is the fruition of our efforts, and we are excited to launch ZORYVE, with expected product availability by mid-August."

Topical therapies remain the primary treatment option for the vast majority of individuals with plaque psoriasis, a common immune-mediated skin disease that affects approximately nine million people in the U.S. and is the most frequent type of psoriasis occurring in both adults and adolescents. Severity can range between mild, moderate, and severe, with itch being the most burdensome and frequently reported symptom.

While the disease may affect any area of the body, plaques in certain areas, like the face, elbows and knees, genitalia, and intertriginous areas (areas of skin-to-skin contact), present unique treatment challenges. As a result, individuals with psoriasis are often prescribed multiple topical medications for different areas, which makes for a complicated treatment regimen.

"In multiple clinical trials, ZORYVE was proven to be safe and effective, with improvements in disease clearance in hard-to-treat areas like knees and elbows, as well as in sensitive areas such as the face, genitalia, and intertriginous areas. ZORYVE is very well tolerated, which is an important consideration for treating a chronic skin disease such as plaque psoriasis," said Mark Lebwohl M.D., FAAD, principal investigator and Dean for Clinical Therapeutics and Chairman Emeritus of the Kimberly and Eric J. Waldman Department of Dermatology at the Icahn School of Medicine at Mount Sinai. "With this FDA approval, adults and adolescents with psoriasis and their dermatologists have a new steroid-free treatment option for use on all affected areas of the body."

ZORYVE features HydroARQ Technology™, a proprietary drug delivery formulation that creates a non-greasy moisturizing cream that spreads easily and absorbs quickly.

"Plaque psoriasis is a challenging disease and finding the right treatment option can be complicated, especially if individuals have to use multiple treatments for different parts of their body. We welcome a new treatment option that can make a meaningful difference for adults and adolescents with plaque psoriasis," says Leah M. Howard, President and CEO of the National Psoriasis Foundation. "Our hope is that new treatments translate into improved outcomes and help alleviate the burdens of chronic disease for people impacted by psoriasis."

Arcutis intends to make ZORYVE widely available via key wholesaler and national dermatology pharmacy channels as a new treatment option by mid-August, and the Company is dedicated to affordable access to therapy. The ZORYVE Direct patient support program will help commercially insured individuals with plaque psoriasis get access and start ZORYVE treatment as prescribed by their healthcare provider quickly and easily by helping them navigate the payer process, lowering the out-of-pocket cost for eligible patients, and offering programs that support staying on therapy.† Arcutis will also offer the Arcutis Cares patient assistance program (PAP) – the first of its kind for a topical psoriasis treatment – that will provide ZORYVE at no cost for financially eligible patients who are uninsured or underinsured.‡

With this approval, Arcutis has access to, and plans to draw, an additional $125 million tranche as part of the Company's non-dilutive financing agreement with SLR Capital Partners. Combined with the Company's cash, cash equivalents, restricted cash, and marketable securities as of June

30, 2022, this additional $125 million will provide for capital resources of over $400 million to support the launch and commercialization efforts for ZORYVE, as well as continue to advance the Company's pipeline development initiatives.

Management will host a conference call on Monday, August 1 at 8:30 a.m. EDT. Dial-in information for conference participants may be obtained by registering for the event here. A live webcast of the call and presentation material will be available on the "Events" section of the Company's Investor website. An archived version of the webcast will be available on the Arcutis website after the call.

A Media Snippet accompanying this announcement is available by clicking on the image or link below:

ZORYVE Clinical Data

The approval is based on comprehensive results from the pivotal DERMIS-1 and DERMIS-2 (trials of P**DE**4 inhibition with **R**oflumilast for the **M**anagement of plaque psorias**IS** One and Two) Phase 3 studies. In these trials, significantly more patients treated with ZORYVE achieved Investigator Global Assessment (IGA) success at Week 8 compared to vehicle (42% in DERMIS-1 and 37% in DERMIS-2 with ZORYVE compared to 6% in DERMIS-1 and 7% in DERMIS-2 with vehicle (P<0.0001 in both studies)). IGA success is defined as an IGA score of clear (0) or almost clear (1), plus a ≥2-grade IGA score improvement from baseline.

ZORYVE improved the severity and impact of itch, as early as Week 2. Two-thirds of patients with a Worst Itch-Numerical Rating Score (WI-NRS) of 4 or higher at baseline achieved a ≥ 4-point reduction in itch at Week 8 with ZORYVE (67% vs. 26% in DERMIS-1 and 69% vs. 33% in DERMIS-2 at Week 8 (P<0.0001)).

ZORYVE is the only topical for which efficacy has been specifically demonstrated in the treatment of intertriginous psoriasis, as measured by Intertriginous IGA (I-IGA) Success (72% vs. 14% in DERMIS-1 and 68% vs. 17% in DERMIS-2 at Week 8 (P<0.0001)).

In both trials, ZORYVE was very well-tolerated with a favorable safety and tolerability profile. The most common adverse reactions reported in DERMIS-1 and -2 (≥1% of subjects treated with ZORYVE for 8 weeks), and for which the rate exceeded the rate for vehicle-treated patients, included diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Of 239 individuals who continued treatment with ZORYVE for at least 52 weeks in an open-label long-term safety trial, 45% were evaluated as an IGA of "Clear" or "Almost Clear" at Week 52.

ZORYVE also demonstrated statistically significant improvements over vehicle on key secondary endpoints, including Psoriasis Area Severity Index-75 (PASI-75), and patient perceptions of signs and symptoms, such as itching, pain, and scaling, as measured by the Psoriasis Symptoms Diary (PSD). In both studies, ZORYVE improved overall signs and symptoms of psoriasis at Weeks 4 and 8 compared to vehicle.

Dr. Lebwohl reports receiving grant support and consulting fees from Arcutis Biotherapeutics.

About Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately nine million people in the United States. The majority of individuals with psoriasis develop "plaques," or raised, red areas of skin covered with a silver or white layer of dead skin cells. The plaques' clinical presentation may have more grayish, purplish, or brownish tones in people with darker skin tones. Psoriatic plaques are often itchy and sometimes painful and can appear on any area of the body. Plaques in certain anatomical areas present unique treatment challenges, including the face, elbows and knees, scalp, and intertriginous areas (where two skin areas may touch or rub together).

INDICATION

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 plaque 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; the Company's expected timing and plan to commercially launch ZORYVE by mid-August; and the Company's plan to draw down on its loan agreement. 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