Arcutis' ZORYVE® (roflumilast) Topical Foam 0.3% Approved by U.S. FDA for the Treatment of Plaque Psoriasis in Adults and Adolescents Ages 12 and Older

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- Once-daily ZORYVE foam provides powerful clearance and rapid itch relief from head to toe with no limitation on duration of use
- More than half of the nearly 9 million people in the United States with plaque psoriasis experience scalp involvement
- Healthcare providers and individuals with plaque psoriasis can now choose ZORYVE foam or cream to treat plaque psoriasis anywhere it appears on the body
- Fifth FDA approval for ZORYVE in less than three years
- Management will host an investor event with a key opinion leader on Monday, June 2 at 8:00 am ET/5:00 am PT

WESTLAKE VILLAGE, Calif., May 22, 2025 (GLOBE NEWSWIRE) -- **Arcutis Biotherapeutics, Inc.** (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the U.S. Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for ZORYVE® (roflumilast) topical foam 0.3% for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older. ZORYVE foam is a once-daily, steroid-free topical and is now widely available as a treatment for plaque psoriasis.

Nearly 9 million people in the United States are living with plaque psoriasis, with over half having scalp involvement and even more presenting with the disease in other hair-bearing areas. These lesions may be difficult to treat with cream or ointments, which can be inconvenient and messy to apply to skin when hair is present. Itch is the most burdensome symptom of psoriasis and can occur anywhere on the body, but occurs more commonly in patients with scalp disease where it is particularly challenging to manage. In clinical trials, ZORYVE foam 0.3% demonstrated significant improvements in signs and symptoms of psoriasis on both the body and scalp, with positive results across all efficacy endpoints, and was safe and well tolerated.

"Treating plaque psoriasis in areas like the scalp, face, and groin is especially challenging. A safe, effective foam offers a much-needed solution," said Jennifer Soung, MD, director of clinical research at Southern California Dermatology, and clinical trial investigator. "In clinical trials, ZORYVE foam not only effectively cleared psoriasis plaques on the body and scalp, but also provided rapid itch relief. ZORYVE can be safely used for any duration and offers two highly convenient formulations, cream or foam, for healthcare providers to choose from. ZORYVE foam allows patients to treat their whole body with one prescription, transforming the treatment landscape for scalp and body psoriasis."

"Individuals living with psoriasis, a chronic inflammatory skin disease, want treatments that are not only safe and effective for long-term use but also convenient. With approval for cream and now the foam formulations, individuals and clinicians can choose their preferred administration of ZORYVE with powerful, long-term relief of plaques and itch anywhere on the body, including hair-bearing areas, with no limitation on duration of use," said Frank Watanabe, president and chief executive officer of Arcutis. "Leveraging our deep medical dermatology expertise, we intentionally formulated ZORYVE to meet the needs of individuals with psoriasis, including hard-to-treat areas from head to toe. This is the fifth approval for ZORYVE in less than three years and furthers our mission to deliver new treatment options that address the urgent needs of individuals suffering from chronic inflammatory skin diseases."

"Living with plaque psoriasis can have a profound impact on people's emotional well-being, quality of life, and social relationships. This can be even further exacerbated when psoriasis appears on the face, scalp, or thin-skinned areas," said Leah Howard, president and chief executive officer, National Psoriasis Foundation. "We are pleased to see new advancements and innovation in treatments for the millions afflicted with this serious skin disease, that can be used long-term and anywhere the disease presents."

ZORYVE foam 0.3% is also approved for the treatment of seborrheic dermatitis and is widely available today via key wholesaler and dermatology pharmacy channels. Arcutis is dedicated to ensuring predictable access for the entire ZORYVE portfolio of products, with one simple copay and fulfillment process. The ZORYVE® Direct Program helps patients access their prescribed Arcutis medication. Specifically, this patient support program helps those who have been prescribed ZORYVE to navigate the payer process, assists patients with adherence, and includes the ZORYVE Direct Savings Card Program, which can help reduce out-of-pocket costs for eligible commercially insured patients.† Arcutis will also continue to offer the Arcutis Cares™ patient assistance program (PAP) that provides ZORYVE at no cost for financially eligible patients who are uninsured or underinsured.‡

Management will host a virtual Key Opinion Leader Event for investors and analysts on Monday, June 2 at 8:00 am ET, featuring a leading dermatology and immune-mediated skin disease expert who will discuss the unmet need and current treatment landscape for individuals with plaque psoriasis. A registration link for the call is available on the "Events" section of the Company's Investor website. An archived version of the webcast and slides will be available on the Arcutis website after the call.

A Media Snippet accompanying this announcement is available in this link.

Clinical Data

The approval is supported by positive results from Arcutis' Phase 2 and pivotal Phase 3 trials in plaque psoriasis. The " A Randomized tRial Employing topiCal roflumilasT foam to treat scalp psORIasis" (ARRECTOR) and the Phase 2 (Trial 204) were multicenter, randomized, double-blind, vehicle-controlled studies evaluating the safety and efficacy of ZORYVE foam 0.3% in plaque psoriasis. Together the two studies enrolled 736 adults and

adolescents ages 12 years and older with mild to severe plaque psoriasis of scalp and body. In each trial, subjects were randomized 2:1 to receive ZORYVE foam 0.3% or vehicle foam applied once daily for 8 weeks.

The ARRECTOR study met its co-primary endpoints of Scalp-Investigator Global Assessment (S-IGA) Success and Body-Investigator Global Assessment (B-IGA) Success. For Scalp-IGA, 66.4% of individuals treated with ZORYVE foam compared to 27.8% of individuals treated with a matching vehicle foam achieved Scalp-IGA Success at Week 8 (P<0.0001). For Body-IGA, 45.5% of individuals treated with ZORYVE foam compared to 20.1% of individuals treated with a matching vehicle foam achieved Body-IGA Success at Week 8 (P<0.0001). IGA Success was defined as an IGA score of 'clear' or 'almost clear' plus a 2-point improvement from baseline.

Trial 204 met its primary endpoint with 56.7% of individuals treated with ZORYVE foam achieving S-IGA Success compared to 11.0% of individuals treated with a matching vehicle foam at Week 8 (P<0.0001). In addition, 39.0% of individuals treated with ZORYVE foam achieved B-IGA Success compared to 7.4% of individuals treated with a matching vehicle foam at Week 8 (P<0.0001).

ZORVYE foam provided a clinically meaningful improvement in itch. In ARRECTOR, two thirds (65.3%) of individuals treated with ZORYVE achieved a clinically significant reduction in scalp itch compared to approximately one third (30.3%) of individuals treated with vehicle at Week 8 (P<0.0001) as measured by a ≥ 4-point change from baseline in Scalp Itch-Numeric Rating Scale (SI-NRS). Importantly, a greater improvement in scalp itch was observed 24 hours following the first application with ZORYVE foam compared to vehicle (as measured by mean SI-NRS change from baseline, relative to vehicle; P=0.0164). The improvement in scalp itch was consistent in Trial 204, with a higher percentage of individuals achieving SI-NRS Success at Week 8 with ZORYVE foam compared to vehicle (67.3% vs. 20.7%).

In addition, the ZORYVE foam also provided improvement in body itch as measured by the Worst Itch-Numeric Rating Scale (WI-NRS), with 63.1% of those treated with ZORYVE foam achieving a ≥ 4-point reduction in WI-NRS compared to 30.1% of those treated with vehicle at Week 8 (P<0.0001) in ARRECTOR.

ZORYVE foam 0.3% was well tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and generally similar between active treatment and vehicle, with most TEAEs assessed as mild to moderate severity. Overall, the most common adverse reactions for ZORYVE foam for plaque psoriasis in the Phase 3 and Phase 2 studies combined (≥1%) included headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%). Rates of discontinuation due to adverse events were low and similar among ZORYVE-treated and vehicle-treated patients in pooled vehicle-controlled studies.

About Plaque Psoriasis
Psoriasis is a common, chronic, inflammatory skin disease that affects nearly 9 million people in the United States. Symptoms include itch, scaling, redness, and flaking. On darker skin tones, plaques may appear more grayish, purplish, or brown. Psoriasis can appear anywhere on the body, including the knees, elbows, torso and thin-skinned areas like the face, genitals and intertriginous areas, which are areas where skin touches skin, such as the armpits, under the breasts, stomach folds, between the buttocks, and in the groin area. In addition, scalp psoriasis sometimes extends to the forehead, back of the neck, or behind or inside the ears. 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 ZORYVE (roflumilast)
ZORYVE is a next generation topical phosphodiesterase-4 (PDE4) inhibitor. PDE4 – an established target in dermatology – is an intracellular enzyme that increases the production of pro-inflammatory mediators and decreases production of anti-inflammatory mediators. Roflumilast cream 0.3% (ZORYVE®) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Roflumilast cream 0.15% (ZORYVE®) is approved by the FDA for the topical treatment of mild to moderate atopic dermatitis in patients 6 years of age and older. In 2024, ZORYVE cream 0.15% was awarded *Glamour's* Beauty and Wellness Award for "Eczema Product." ZORYVE (roflumilast) topical foam 0.3% is uniquely formulated for use anywhere on the body, including hair-bearing areas, and is indicated for treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older. ZORYVE is the first and only branded topical therapy for three major inflammatory dermatoses - including atopic dermatitis, seborrheic dermatitis, and plaque psoriasis.

INDICATIONS

ZORYVE topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

ZORYVE cream, 0.3%, is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older.

ZORYVE cream, 0.15%, is indicated for topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.

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

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for plaque psoriasis include headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for seborrheic dermatitis include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

The most common adverse reactions (≥1%) for ZORYVE cream 0.3% for plaque psoriasis include diarrhea (3.1%), headache (2.4%), insomnia (1.4%), nausea (1.2%), application site pain (1.0%), upper respiratory tract infection (1.0%), and urinary tract infection (1.0%).

The most common adverse reactions (≥1%) for ZORYVE cream 0.15% for atopic dermatitis include headache (2.9%), nausea (1.9%), application site pain (1.5%), diarrhea (1.5%), and vomiting (1.5%).

Please see full Prescribing Information for ZORYVE foam and full Prescribing Information for ZORYVE cream.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a 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 of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis' unique dermatology development platform coupled with our dermatology expertise allows us to invent differentiated therapies against biologically validated targets, and has produced a robust pipeline with multiple follow-on clinical programs for a range of inflammatory dermatological conditions including atopic dermatitis and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, 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 real-world use results of ZORYVE foam and the potential for ZORYVE to advance the standard of care in plaque psoriasis, atopic dermatitis and seborrheic dermatitis. 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 the U.S. Securities and Exchange Commission (SEC) on February 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

† Subject to eligibility criteria and maximum program limitation. This offer is not valid for patients without commercial drug insurance or whose prescription claims are eligible to be reimbursed, in whole or in part, by any government program.

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

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