Arcutis Announces Publication of Positive Data from ARRECTOR Trial Evaluating ZORYVE® (roflumilast) Foam 0.3% in Individuals with Psoriasis in Journal of American Medical Association Dermatology

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- Once-daily, investigational ZORYVE foam 0.3%, rapidly improved psoriasis of the scalp and body, including itch, when used as a monotherapy
- 66.4% of individuals treated with ZORYVE foam achieved Scalp-Investigator Global Assessment (S-IGA) Success at Week 8
- 45.5% of individuals treated with ZORYVE foam achieved Body-Investigator Global Assessment (B-IGA) Success at Week 8
- Efficacy and safety results were consistent with Phase 2 results of ZORYVE foam 0.3% in adults and adolescents 12 years of age and older
- Supplemental New Drug Application (sNDA) for investigational ZORYVE foam 0.3% for psoriasis is under review with U.S. Food and Drug Administration (FDA) with a Prescription Drug User Fee Act (PDUFA) action date of May 22, 2025
- More than half of the nearly 9 million people in the United States with plaque psoriasis experience scalp involvement

WESTLAKE VILLAGE, Calif., May 07, 2025 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that the *Journal of American Medical Association (JAMA) Dermatology* published the positive results from a pivotal Phase 3 study evaluating the efficacy and safety of ZORYVE® (roflumilast) foam 0.3% as a once-daily monotherapy treatment for psoriasis of the scalp and body.

The study showed that treatment with investigational ZORYVE foam resulted in significant improvements across multiple efficacy endpoints, including the co-primary efficacy endpoints of S-IGA Success and B-IGA Success, as well as key secondary endpoints. The data also show improvement in pruritus (itch) was observed as early as 24 hours after the first application.

“Plaque psoriasis is a chronic and burdensome disease that often leaves people searching for relief from thick scales, itch, and discomfort – especially when it affects the scalp, where treatment can be particularly challenging,” said Melinda Gooderham, MD, MSc, FRCPC, dermatologist and medical director at the SKiN Centre for Dermatology, principal investigator at the SKiN Research Centre, and lead author on the paper. “These compelling results demonstrate that ZORYVE foam 0.3% may provide rapid and significant relief of plaques anywhere on the body and is well-tolerated according to both investigator and patient-reported assessments. The foam formulation is particularly beneficial for its versatility in treating hair-bearing and non-hair-bearing skin, which could ultimately help patients adhere to their treatment.”

A Randomized tRial Employing topiCal roflumilasT foam to treat scalp psORiasis (ARRECTOR), was a Phase 3, randomized, double-blinded, vehicle-controlled trial which enrolled 432 adults and adolescents aged 12 years and older with plaque psoriasis affecting the scalp and body, across 49 sites in the United States and Canada.

Significantly greater proportions of individuals treated with ZORYVE foam 0.3% achieved the co-primary efficacy endpoints of S-IGA Success and B-IGA Success, defined as an IGA score of ‘clear’ or ‘almost clear’ plus a 2-point improvement from baseline. At Week 8, 66.4% of individuals treated with ZORYVE foam 0.3% achieved S-IGA success compared to 27.8% for vehicle (P<0.0001). At Week 8, 45.5% of patients treated with ZORYVE foam achieved B-IGA success compared to 20.1% for vehicle (P<0.0001).

Other key findings include:

- ZORYVE foam provided a clinically meaningful improvement in scalp itch. 65.3% of individuals treated with ZORYVE achieved a clinically significant reduction in itch compared to 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). Significant improvement was seen in the ZORYVE treatment group as early as Week 2. The data also demonstrated improvement in body itch as measured by the Worst Itch-Numeric Rating Scale (WI-NRS) at Week 8, with 63.1% of those treated with ZORYVE foam 0.3% achieving a ≥ 4-point reduction in WI-NRS compared to 30.1% of those treated with vehicle (P<0.0001). Significant improvement was seen in the ZORYVE treatment group as early as Week 2.
- Importantly, there was a greater improvement in itch observed with ZORYVE within 24 hours after the first application compared to vehicle (as measured by mean SI-NRS change from baseline, relative to vehicle; P=0.0164). This improvement over vehicle within 24 hours after the first application was also observed in body itch (as measured by WI-NRS change from baseline, relative to vehicle; nominal P=0.0094).
- At Week 8, 70.9% of those treated with ZORYVE foam versus 31.3% treated with vehicle achieved at least 75% improvement in Psoriasis Scalp Severity Index (PSSI-75) (P<.001), another secondary endpoint.
- Similarly, 50.1% of people treated with ZORYVE foam 0.3% achieved at least 75% improvement in Psoriasis Area and Severity Index (PASI-75), a key secondary endpoint, as compared to 16.8% of those treated with vehicle at Week 8

(P<.001).

ZORYVE foam was well-tolerated. The incidence of Treatment Emergent Adverse Events (TEAEs) was low and similar in both active treatment and vehicle arms. The most frequent adverse events in the ZORYVE foam arm (≥1%) included headache, diarrhea, and nausea. Investigator-rated application-site tolerability was similar between ZORYVE and vehicle groups, with investigators reporting no evidence of irritation for at least 99.2% of all patients at all time points. Patient-rated application-site tolerability was also similar between ZORYVE and vehicle with at least 94.4% of patients reporting no or mild sensation on local tolerability assessments at all time points.

"We are thrilled that *JAMA Dermatology*, a premier medical journal, has published the positive results of our pivotal ARRECTOR study. These data demonstrate that investigational ZORYVE foam rapidly relieved psoriasis symptoms, including the most troublesome symptom of itch," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. "As an effective, safe, and well-tolerated once-daily treatment, ZORYVE foam 0.3%, if approved, will offer those living with psoriasis a potential new treatment option for use anywhere on the body with no limitations on duration of use. Having a single agent that effectively treats psoriasis on both the scalp and body, with a safe and tolerable profile, is an important therapeutic benefit for both clinicians and the people they treat. We look forward to the FDA's potential approval of ZORYVE foam 0.3% for the treatment of plaque psoriasis of the scalp and body anticipated later this month."

About Plaque Psoriasis
Psoriasis is a common, chronic, inflammatory skin disease that affects approximately nine 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 areas where the skin is thin, 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 occurs in more than half of all psoriasis sufferers, and sometimes extends to the forehead, back of the neck, or behind or inside the ears.

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. ZORYVE (roflumilast) topical foam 0.3% is indicated for treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older. ZORYVE foam is under review for the treatment of scalp and body psoriasis by the FDA with a PDUFA target action date of May 22, 2025. ZORYVE® (roflumilast) cream 0.3% is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. ZORYVE® (roflumilast) cream 0.15% 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) cream 0.05% is under review for the treatment of atopic dermatitis in children ages 2 to 5 by the FDA, with a PDUFA target action date of October 13, 2025.

INDICATIONS

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.

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

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%).

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 in scalp and body psoriasis, the potential for ZORYVE foam to advance the standard of care in plaque psoriasis, atopic dermatitis and other inflammatory dermatological conditions, as well as potential regulatory approvals and associated timing of such approvals. 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.

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