FDA Accepts Arcutis' Supplemental New Drug Application for ZORYVE® (roflumilast) Foam for the Treatment of Scalp and Body Psoriasis in Adults and Adolescents Ages 12 and Over

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- U.S. Food and Drug Administration (FDA) has set a Prescription Drug User Fee Act (PDUFA) target action date of May 22, 2025
- Almost half of the 9 million individuals in the United States with plaque psoriasis experience involvement of the scalp
- Supplemental New Drug Application (sNDA) supported by positive efficacy and safety data from Phase 2b and pivotal Phase 3 trials, and long-term ZORYVE cream plaque psoriasis program

WESTLAKE VILLAGE, Calif., Sept. 24, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the FDA has accepted its sNDA for ZORYVE (roflumilast) foam 0.3%, a once-daily, next generation phosphodiesterase-4 (PDE4) inhibitor, for the treatment of adults and adolescents ages 12 and over with scalp and body psoriasis. The FDA assigned the application a PDUFA target action date of May 22, 2025.

"In clinical studies, investigational once-daily ZORYVE foam has demonstrated significant improvements in psoriasis signs and symptoms, effectively and reliably improving both scalp and body psoriasis across all efficacy endpoints compared to vehicle," said Jennifer Soung, MD, director of clinical research at Southern California Dermatology, and clinical trial investigator. "Almost half of individuals with plaque psoriasis experience it on their scalp, accompanied by itchy and sometimes painful plaques, often along with plaques elsewhere on the body. Scalp symptoms can be especially burdensome to manage because hair-bearing areas present unique challenges in terms of treatment application that are not easily addressed with traditional creams or ointments, as they can be inconvenient and messy when used to treat scalp psoriasis. The unique formulation of ZORYVE foam is potentially a transformative new treatment option, if approved, for those living with scalp and body psoriasis."

"ZORYVE foam, if approved, would represent a truly meaningful innovation for millions of people with scalp and body psoriasis whose symptoms have not been adequately addressed by existing treatments," said Frank Watanabe, president and chief executive officer of Arcutis. "We look forward to working closely with the FDA during the review process for our fifth topical roflumilast regulatory submission in the United States in less than three years. This filing acceptance is a critical milestone in our mission to deliver new treatment options that address the urgent needs of individuals living with immune-mediated diseases and conditions."

The sNDA is supported by positive results from Arcutis' pivotal ARRECTOR Phase 3 trial, a Phase 2b study, and long-term efficacy and safety data generated from the ZORYVE cream development program in plaque psoriasis.

The "A Randomized tRial Employing topiCal roflumilasT foam to treat scalp psORiasis" (ARRECTOR) study was a parallel group, double-blind, vehicle-controlled pivotal Phase 3 study of the safety and efficacy of roflumilast foam 0.3% or a matching vehicle administered once-daily in individuals ages 12 and older with plaque psoriasis of the scalp and body (n=432). The study met its co-primary endpoints with 66.4% of individuals treated with roflumilast foam achieving Scalp-Investigator Global Assessment (S-IGA) Success (IGA Success is defined as an IGA score of 'clear' or 'almost clear' plus a 2-point improvement from baseline) compared to 27.8% of individuals treated with a matching vehicle foam at Week 8 (P<0.0001), and 45.5% of individuals treated with roflumilast foam achieved Body-Investigator Global Assessment (B-IGA) Success compared to 20.1% of individuals treated with a matching vehicle foam at Week 8 (P<0.0001).

Two thirds (65.3%) of roflumilast-treated patients with clinically meaningful itch at baseline achieved a clinically significant reduction in itch compared to 30.3% of vehicle-treated patients at Week 8 (P<0.0001) as measured by a ≥ 4-point change from baseline in Scalp Itch-Numeric Rating Scale (SI-NRS). Importantly, some patients experienced rapid relief in scalp itch 24 hours following first application compared to vehicle (as measured by mean SI-NRS change from baseline, relative to vehicle; P=0.0164).

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

Roflumilast 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 roflumilast foam in the phase 3 and phase 2b studies (≥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 roflumilast-treated and vehicle-treated patients in pooled vehicle-controlled studies.

About Scalp and Body Psoriasis
Scalp psoriasis is a manifestation of plaque psoriasis and sometimes extends to the forehead, back of the neck, or behind or inside the ears. Plaque psoriasis is characterized by raised, red areas of skin ("plaques") covered with a silver or white scale. Individuals with scalp psoriasis commonly have plaques on other areas of the body as well. Almost half of the estimated 9 million Americans with plaque psoriasis have scalp involvement. Scalp psoriasis plaques are identical to psoriatic plaques on other areas of the body; however, topical treatment of scalp plaques is further complicated by the need to deliver drugs onto the affected skin in hair bearing areas where traditional cream and ointment formulations can be difficult to apply. As with psoriatic plaques on other parts of the body, psoriasis on the scalp is often itchy and is sometimes painful. 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. Often, individuals require two or more medications to manage their disease when they have scalp involvement.

About ZORYVE (roflumilast) Foam
Roflumilast foam is a once-daily topical foam formulation of roflumilast, a next generation topical 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 foam is uniquely formulated for use anywhere on the body, including hair-bearing areas. ZORYVE is the first and only branded topical therapy for three major inflammatory dermatoses.

Indications
ZORYVE 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 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 including three FDA approved products that harness 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, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

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 of roflumilast foam and regulatory timing for FDA approval based on the PDUFA for the treatment of scalp and body psoriasis; the potential of real-world use results of roflumilast foam, as well as the potential approval of roflumilast foam for scalp and body 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 the U.S. Securities and Exchange Commission (SEC) on February 27, 2024, 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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