Arcutis Launches ZORYVE® (roflumilast) Cream 0.15% for the Treatment of Atopic Dermatitis

July 29, 2024

- Once-daily, effective, safe, and well-tolerated ZORYVE cream now commercially available
- Provides rapid clearance of atopic dermatitis signs and symptoms and significant reduction in itch, and can be used anywhere on the body for any duration to maintain clear skin
- Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States
- Management will host an investor event with a key opinion leader on Monday, July 29 at 8:30 am EDT/5:30 am PDT

WESTLAKE VILLAGE, Calif., July 29, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the commercial launch of ZORYVE® (roflumilast) cream 0.15% for the treatment of mild to moderate atopic dermatitis in adults and children down to age 6 in the United States. ZORYVE is a once-daily, steroid-free cream that provides rapid disease clearance and significant reduction in itch, and was developed to provide long-term disease control.

"Atopic dermatitis is a complex disease that affects tens of millions of adults and children in the United States. While topical therapies are often prescribed to treat this chronic disease, they come with limitations on duration of use or side effects that require careful management. ZORYVE is a once-daily cream developed with the atopic dermatitis patient in mind, that can effectively and safely be used to relieve symptoms anywhere on the body," said Todd Edwards, chief commercial officer at Arcutis. "We are thrilled to announce the availability of ZORYVE for atopic dermatitis, which marks our third commercial launch in two years. ZORYVE cream 0.15% joins our portfolio of ZORYVE products, all of which can be easily accessed through pharmacies and our high-quality payor coverage."

ZORYVE cream 0.15% will be available in pharmacies this week. ZORYVE cream is listed as a line extension within two commercial PBM contracts, providing immediate insurance coverage for many patients.

"The yet-to-be-satisfied goal for atopic dermatitis treatment is the establishment of long-term disease control by a therapy that is well tolerated by patients and also effective in both reducing inflammation as well as the most burdensome symptom in atopic dermatitis - itch. The unique formulation of ZORYVE cream helps to deliver the active ingredient while avoiding excipients that commonly cause skin barrier disruption, irritation, or contact allergy, which makes it well-suited for long-term continuous use in the treatment of this chronic inflammatory condition," said Rocco Serrao MD, FAAD.

Arcutis is dedicated to responsible pricing and affordable access to therapy, while ensuring predictable access for the ZORYVE portfolio of products, with one simple copay and fulfillment process across all ZORYVE products. 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.‡

On July 9, 2024, Arcutis announced that the U.S. Food and Drug Administration (FDA) had approved ZORYVE cream 0.15% for the topical treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older. ZORYVE is available by prescription only. For more information about ZORYVE visit zoryve.com.

Management will host a conference call on Monday, January 29 at 8:30 am EST, featuring a leading dermatology and immune-mediated skin disease expert to discuss the unmet need and current treatment landscape for individuals with mild to moderate atopic dermatitis. 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.

About Atopic Dermatitis
Atopic dermatitis is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States.

Atopic dermatitis is a chronic, relapsing inflammatory skin disease that is genetically pre-disposed and presents across the lifespan. The disease appears as a red, intensely itchy rash that can occur anywhere on the body, and may present differently in children and adults. Atopic dermatitis presentation can rapidly fluctuate and vary based on geographic location and environment.

About ZORYVE®
ZORYVE is a steroid-free topical phosphodiesterase 4 (PDE4) inhibitor approved to treat atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. 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) cream 0.15% is approved by the FDA for the treatment of mild to moderate atopic dermatitis in individuals 6 years of age and older, and ZORYVE cream 0.3% for the topical treatment of plaque psoriasis in individuals 6 years of age and older. Another formulation, ZORYVE foam, 0.3%, is available for the treatment of seborrheic dermatitis in adults and children ages 9 and older.

Roflumilast cream for atopic dermatitis is currently being evaluated at a lower dose of 0.05% for children aged 2 to 5 years. In addition, Arcutis has submitted a supplemental new drug application for ZORYVE foam 0.3% for the treatment of scalp and body psoriasis.

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 cream and full Prescribing Information for ZORYVE foam.

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 real-world use results of ZORYVE cream in atopic dermatitis, the potential for ZORYVE cream to advance the standard of care in atopic dermatitis and other inflammatory dermatological conditions, as well as the commercial launch of ZORYVE cream in atopic dermatitis by the end of July, 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, 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 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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† 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