ZORYVE® (roflumilast) Topical Foam, 0.3%, for the Treatment of Seborrheic Dermatitis Launches in the United States

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- First drug approved for seborrheic dermatitis with a new mechanism of action in over two decades available in pharmacies this week
- Effective, safe, and very well-tolerated steroid-free foam provides rapid disease clearance and significant reduction in itch
- Seborrheic dermatitis affects more than 10 million people in the United States
- Management will host conference call on Monday, January 22 at 1:30 pm PST/4:30 pm EST

WESTLAKE VILLAGE, Calif., Jan. 22, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the launch of ZORYVE® (roflumilast) topical foam, 0.3%, in the United States for the treatment of seborrheic dermatitis in individuals 9 years of age and older. ZORYVE is a once-daily steroid-free foam and is the first drug approved for seborrheic dermatitis with a new mechanism of action in over two decades.

“Despite being a very common condition with significant negative impact on quality of life, seborrheic dermatitis has largely been overlooked by the pharmaceutical industry,” said Todd Edwards, chief commercial officer at Arcutis. “We are proud to launch our second commercial product in the United States and have it immediately available in pharmacies with strong reimbursement from the major pharmacy benefit managers through our already established contracts.”

“Following decades without significant innovation in seborrheic dermatitis treatment, it’s exciting to have an approved, targeted treatment option for such a common yet burdensome inflammatory disease. ZORYVE foam possesses several unique qualities that address unmet needs of seborrheic dermatitis patients. Notably, ZORYVE foam offers once-daily application, a water-based foam vehicle that can be used anywhere on the body, and versatility for use across all skin and hair types as well as the full spectrum of disease severity,” said Raj Chovatiya, MD, PhD, MSCI, a board-certified dermatologist and clinical investigator based in Chicago. “In clinical trials, ZORYVE foam provided complete clearance for more than half of all subjects, and 3 in 4 patients achieved IGA treatment success at 8 weeks, with greater than 40% achieving IGA treatment success as early as two weeks. Based on these key attributes, ZORYVE foam has the potential to define a new standard of care for seborrheic dermatitis.”

ZORYVE foam will be available via wholesaler and pharmacy channels this week. ZORYVE foam is listed as a line extension within key commercial PBM contracts, which will provide the opportunity for rapid formulary access.

The ZORYVE® Direct Program helps patients access their prescribed Arcutis medication. For patients with seborrheic dermatitis who have been prescribed ZORYVE, this patient support program helps patients 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 December 15, 2023, Arcutis announced that the U.S. Food and Drug Administration (FDA) had approved ZORYVE foam for the treatment of seborrheic dermatitis in individuals 9 years of age and older.

Management will host a conference call on Monday, January 22 at 1:30 pm PST/4:30 pm EST. 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.

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 two 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, and X.

INDICATION
ZORYVE foam, 0.3%, is indicated for 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%) include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

Please see full Prescribing Information.

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 ZORYVE foam to simplify disease management for care of seborrheic dermatitis, potential of ZORYVE foam to become the standard of care in seborrheic dermatitis treatment, and the commercial launch of ZORYVE foam in seborrheic dermatitis, 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 28, 2023, 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