Arcutis Announces Health Canada Approval of ZORYVE® (Roflumilast) Foam 0.3% to Treat Seborrheic Dermatitis in Individuals 9 Years of Age and Older

October 18, 2024

- ZORYVE foam represents the first topical treatment for seborrheic dermatitis with a new mechanism of action approved in Canada in over two decades[1]
- Second approval of ZORYVE outside of the United States, expanding ZORYVE portfolio availability to over 2 million Canadians living with seborrheic dermatitis

WESTLAKE VILLAGE, Calif., Oct. 18, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced that its wholly-owned subsidiary Arcutis Canada, Inc. has received regulatory approval from Health Canada for ZORYVE (roflumilast) topical foam 0.3% for the treatment of seborrheic dermatitis in patients 9 years of age and older. The full Canadian product monograph for ZORYVE is available here.

Over 2 million Canadians are impacted by seborrheic dermatitis, a common, recurrent inflammatory skin condition. ZORYVE foam 0.3% is the first topical treatment for seborrheic dermatitis with a novel mechanism of action approved in Canada in over 20 years.[1]

“ZORYVE foam has made a meaningful impact on the lives of individuals living with seborrheic dermatitis since launching in the United States at the beginning of this year, with rapid adoption by both clinicians and patients. We are proud to bring this safe, effective, and well-tolerated steroid-free foam to Canada, as there has been a lack of innovation for the treatment of seborrheic dermatitis for decades,” said Frank Watanabe, president and CEO of Arcutis. “We would like to thank the Canadian investigators and patients who participated in our ZORYVE clinical trials and who played a critical role in bringing this potential best-in-class topical treatment to the United States and Canada markets.”

“For individuals living with this chronic, inflammatory skin condition, seborrheic dermatitis can have a profound impact on quality of life. The face and scalp are often red and scaly, which may result in social distancing and consequently affects emotional and psychological wellbeing. Itch, commonly associated with seborrheic dermatitis, may not be apparent through the day but will impair sleep resulting in sleep deprivation. Until today, we lacked the ability to offer effective and safe treatments that are formulated to be both well-tolerated and suitable for once-daily simple application,” said Kim A. Papp, MD, PhD, of Probity Medical Research and K. Papp Clinical Research Inc., and an investigator for the ZORYVE foam clinical trials. “In the STRATUM trial, approximately 80% of patients achieved treatment success at Week 8 with ZORYVE foam, with disease clearance as early as Week 2, and significant itch relief in as little as 48 hours. Importantly, ZORYVE foam is formulated to deliver the drug without disrupting the skin barrier.”

The approval of ZORYVE foam 0.3% for seborrheic dermatitis in Canada was supported by positive results from a vehicle-controlled pivotal Phase 3 study (STRATUM), as well as a Phase 2 study, a long-term open-label extension study, and a Phase 1 pharmacokinetic study.

About ZORYVE Foam
Arcutis has developed both topical cream and foam formulations of roflumilast, a highly potent and selective phosphodiesterase-4 (PDE4) inhibitor being investigated as a once-daily, nonsteroidal, topical treatment for multiple dermatologic conditions. 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. The approval of ZORYVE foam by Health Canada marks the second approval for Canada of the ZORYVE portfolio. Roflumilast cream 0.3% (^{Pr}ZORYVE®) is approved in Canada for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

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.

INDICATIONS (UNITED STATES)
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 (UNITED STATES)
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.

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 availability of roflumilast foam in Canada for the treatment of adults and adolescents with seborrheic dermatitis, the potential for roflumilast foam to enhance available options for seborrheic dermatitis, the potential to use roflumilast foam anywhere on the body, including the face and scalp, the potential treatment results based on real-world clinical practice, the potential to use roflumilast foam over a long period of time or chronically, and the potential for roflumilast foam to advance the standard of care in seborrheic dermatitis and other inflammatory dermatological conditions. 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
media@arcutis.com

Investors
Latha Vairavan, Vice President, Finance and Corporate Controller
ir@arcutis.com

1. Blauvelt A, Draelos ZD, Stein Gold L, et al. Roflumilast foam 0.3% for adolescent and adult patients with seborrheic dermatitis: A randomized, double-blinded, vehicle-controlled, phase 3 trial. *J Am Acad Dermatol*. 2024;90(5):986-993. doi:10.1016/j.jaad.2023.12.065

2. Data on file. Arcutis Biotherapeutics, Inc.

3. Jackson JM, Alexis A, Zirwas M, Taylor S. Unmet needs for patients with seborrheic dermatitis. *J Am Acad Dermatol*. 2024;90(3):597-604. doi:10.1016/j.jaad.2022.12.017