# Arcutis Announces Canadian Approval of ZORYVE™ (roflumilast) Cream 0.3% for Treatment of Plaque Psoriasis in Individuals 12 Years and Older

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- *First novel steroid-free topical with a new mechanism of action approved for plaque psoriasis in over 25 years*
- *First ZORYVE approval outside of the U.S. marks key milestone for Arcutis*

WESTLAKE VILLAGE, Calif., April 28, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, announced today that its next-generation topical PDE4 inhibitor therapy for plaque psoriasis, ZORYVE™ (roflumilast) cream 0.3%, has received regulatory approval from Health Canada.

In Canada, ZORYVE is indicated for topical treatment of plaque psoriasis, including treatment of psoriasis in the intertriginous areas, in individuals 12 years of age and older. The full Canadian product monograph for ZORYVE is available here.

“The successful approval of ZORYVE in Canada is a testament to Arcutis’ continued commitment to provide therapies that address the most persistent challenges for individuals with immune-mediated skin diseases. We are proud to bring this important new steroid-free cream to Canada, where there is a need for safe and effective topical treatment for plaque psoriasis,” said Frank Watanabe, President and CEO of Arcutis. “We deeply value our ongoing partnership with Canadian dermatologists, who played a central role in the development of ZORYVE, providing approximately one-third of all clinical trials participants, and we look forward to continuing to advance our robust pipeline in both Canada and the United States.”

“Topical agents are the mainstay of treatment for the majority of individuals with plaque psoriasis, and until now there have been limited options suitable for chronic use. ZORYVE demonstrates rapid clearance of plaques anywhere on the body, including harder to treat areas such as the elbows and knees, but is also effective in the sensitive intertriginous areas like under the breasts, in the groin, or under the arms,” said Dr. Melinda Gooderham, Assistant Professor, Queen’s University, Medical Director at the SKiN Centre for Dermatology and Principal Investigator for the SKiN Research Centre in Peterborough, Ontario.

Since 2016, Arcutis Biotherapeutics has successfully built a therapeutic portfolio to deliver meaningful innovation to treat immune-mediated dermatological diseases and conditions. Today’s announcement marks a significant commercial milestone as the first regulatory approval of ZORYVE outside of the United States.

**About ZORYVE®**
ZORYVE (roflumilast) cream 0.3% is a next generation topical inhibitor of phosphodiesterase-4 (PDE4) and the first topical PDE4 inhibitor to be approved by the FDA and Health Canada for adults and adolescents with plaque psoriasis, including intertriginous psoriasis.

**INDICATION (United States)**
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

**IMPORTANT SAFETY INFORMATION (United States)**
The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

Please see full U.S. Prescribing Information.

**About Arcutis**
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a 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 that harnesses 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, seborrheic dermatitis, and alopecia areata. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

**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 for ZORYVE to simplify disease management for care of plaque psoriasis; the potential of real-world use results of roflumilast cream, the Canada commercial launch of ZORYVE in plaque psoriasis, and access and continued expansion in commercial coverage with payers. 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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