Arcutis Announces ZORYVE® U.S. Co-promote Agreement with Kowa Pharmaceuticals America, Inc.

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- Over 200-person sales force to promote ZORYVE (roflumilast) in primary care and pediatric practices
- Provides access to a large portion of the 7.4 million individuals treated for plaque psoriasis, seborrheic dermatitis, and atopic dermatitis outside of dermatology offices
- ZORYVE will be promoted in the primary position to maximize prescriber education

WESTLAKE VILLAGE, Calif. and MONTGOMERY, Ala., 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 signing of a co-promotion agreement with Kowa Pharmaceuticals America, Inc., a company committed to the development and commercialization of safe and effective healthcare solutions. Under the agreement, Kowa will leverage its primary care sales force to market and promote ZORYVE (roflumilast) cream and ZORYVE (roflumilast) foam to primary care practitioners and pediatricians for all FDA approved indications. Arcutis will maintain responsibility for the marketing and sales of ZORYVE to dermatologists, other dermatology clinicians, and related specialists. This partnership is expected to expand the total addressable market for ZORYVE, providing access to a large portion of the 7.4 million patients treated outside of dermatology offices.

“This partnership is aligned with our strategy and significantly extends the reach of ZORYVE to primary care practitioners and pediatricians who treat millions of individuals each year suffering from atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. ZORYVE is well-suited to fit into the daily practice of these offices, as it simplifies disease management with a once-daily, steroid-free treatment option,” said Frank Watanabe, president and CEO of Arcutis. “Sales of ZORYVE continue to grow because it provides reliable efficacy and a safe and well-tolerated product profile, as well as Arcutis’ broad market access. With the new expansion into primary care and pediatrics through this partnership with Kowa, we will drive incremental revenue, while maintaining the focus of Arcutis’ sales force and its marketing efforts on dermatology clinicians and driving patient demand in the dermatology offices. Importantly, Kowa has established relationships in primary care and will promote ZORYVE as a core product throughout the term of the agreement.”

“Kowa Pharmaceuticals America, Inc. has a long history of successfully co-promoting products within primary care, and this new partnership with Arcutis aligns closely with our focus and expertise in the primary care setting,” said Ben Stakely, chairman, CEO, and president of Kowa Pharmaceuticals America, Inc. “We remain committed to patients and healthcare professionals and to providing therapies that help address unmet needs. Adding ZORYVE to our product portfolio expands our offering and will enhance our ability to support patients.”

Arcutis will recognize all revenue and will have sole responsibility for the manufacturing of ZORYVE during the 5-year term of the partnership. Kowa will have an exclusive agreement to promote ZORYVE in all approved formulations and dosage forms as commercialized by Arcutis to primary care clinicians, pediatricians, and certain collocated healthcare providers in the United States throughout the term of the agreement. Kowa will promote ZORYVE in priority position throughout the term of the partnership, and receive a commission on their sales. Financial terms of the agreement were not disclosed.

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 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.

About Kowa Company, Ltd.

Kowa Company, Ltd. (Kowa) is a privately held, multinational company headquartered in Nagoya, Japan. Established in 1894, Kowa is actively engaged in various business fields, including the trading of textiles, machinery, and construction materials, in addition to the manufacturing and sales of pharmaceuticals, medical devices, vison units, energy-saving and energy-creating products. Kowa's pharmaceutical business is focused on research and development for three main activities in lifestyle-related diseases (dyslipidemia, type 2 diabetes, and atherosclerosis), ophthalmology, and anti-inflammatory agents. For more information, please see https://www.kowa.co.jp/eng/.

About Kowa Pharmaceuticals America, Inc.
Kowa Pharmaceuticals America, Inc., headquartered in Montgomery, AL, is focused primarily in the area of primary care diseases. Established in September 2008, Kowa Pharmaceuticals America, Inc. focuses its efforts on the successful commercialization of its current and near-term portfolio of pharmaceutical products, and business development activities. For more information about Kowa Pharmaceuticals America, visit https://www.kowapharma.com/.

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, atopic dermatitis and seborrheic dermatitis; the potential of real-world use results of roflumilast cream, the potential success of the co-promotion agreement with Kowa, the potential for and general ability to access patients treated outside of dermatology offices, as well as the commercial strategy and launches of ZORYVE. 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, and 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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