Arcutis and Sato Announce Strategic Collaboration and Licensing Agreement for Topical Roflumilast in Japan

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- Arcutis to receive a $25 million upfront payment, and is eligible to receive potential development and commercial milestone payments (totaling $40 million), as well as tiered, double-digit royalties
- Agreement offers pathway to potentially offering a novel non-steroidal topical option to the millions of Japanese patients suffering from inflammatory skin diseases

WESTLAKE VILLAGE, Calif. and TOKYO, Feb. 28, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, and Sato Pharmaceutical Co., Ltd., a leading pharmaceutical company, today announced that the companies have entered into a strategic collaboration and licensing agreement for the development, manufacture, and commercialization of topical roflumilast in Japan. Sato will receive an exclusive license for both the cream and foam formulations of topical roflumilast, a next generation phosphodiesterase type 4 (PDE4) inhibitor, for multiple dermatological conditions including plaque psoriasis, seborrheic dermatitis, atopic dermatitis, and potentially additional dermatological conditions in the future.

“We are delighted to partner with Sato, who share our mission to provide meaningful innovation to individuals suffering from immune-mediated skin diseases. This partnership, built on topical roflumilast’s strong product profile, expands the market opportunity for this effective and well-tolerated steroid-free treatment for multiple skin conditions, and provides meaningful non-dilutive capital for us,” said Frank Watanabe, president and chief executive officer, Arcutis. “Sato’s enduring corporate commitment to helping patients achieve a more positive and enjoyable life makes them an ideal partner to bring topical roflumilast to the millions of people suffering from inflammatory skin diseases in Japan.”

“We are excited to partner with Arcutis, a leader in medical dermatology, on the heels of their successful U.S. launches of topical roflumilast in plaque psoriasis and seborrheic dermatitis. We eagerly anticipate the on-going clinical development and potential approvals in atopic dermatitis and scalp psoriasis. Topical roflumilast has been shown to effectively clear skin and reduce itch, with a safe and well-tolerated profile. With this collaboration, we believe we can make an impact for individuals suffering from immune-mediated skin diseases in Japan,” said Seiichi Sato, president and chief executive officer, Sato.

Under the terms of the agreement, Arcutis will receive an upfront payment of $25 million, and potentially an additional $40 million if certain regulatory and sales milestones are achieved. Arcutis is also eligible to receive tiered, low double-digit percentage royalties.

Sato will be responsible for development, manufacturing, and commercialization of roflumilast cream and roflumilast foam and other topical roflumilast presentations in Japan. Arcutis will continue to be responsible for the development and commercialization of ZORYVE® (roflumilast) cream and ZORYVE® (roflumilast) foam in the United States and other geographies, excluding Greater China and Southeast Asia.

About Topical Roflumilast
Arcutis is developing topical cream and foam formulations of roflumilast, a highly potent and selective 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.

INDICATIONS
ZORYVE cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older.

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%) for ZORYVE cream 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 foam 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 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.

About Sato
Sato Pharmaceutical Co., Ltd., operating under its corporate philosophy of “Healthcare Innovation,” is a pharmaceutical company that provides effective, safe, and high-quality products for practicing selfcare, while always keeping the health of its customers in mind. In addition to its main consumer healthcare business, Sato Pharmaceutical also develops and provides highly original products primarily in the field of dermatology.

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 topical roflumilast to simplify disease management; the potential of real-world use results of topical roflumilast, as well as the commercial launch of ZORYVE cream in plaque psoriasis and ZORYVE foam in seborrheic dermatitis in the United States and other geographies. These forward-looking statements also include statements about the development and commercialization of topical roflumilast by our new partner in Japan, the potential receipt of payments associated with achievement of certain milestones, and the potential royalties from sales of commercialized products in Japan. 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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