Arcutis and Huadong Announce Strategic Collaboration and Licensing Agreement for Topical Roflumilast in Greater China and Southeast Asia

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- Arcutis to receive $30 million upfront payment and is eligible to receive potential development and commercial milestone payments, as well as double digit tiered royalties

WESTLAKE VILLAGE, Calif. and HANGZHOU, China, Aug. 10, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, and Hangzhou Zhongmei Huadong Pharmaceutical Co, a wholly owned subsidiary of Huadong Medicine Co., Ltd. (SZ.000963), today announced that the companies have entered into a strategic collaboration and licensing agreement for the development, manufacture, and commercialization of topical roflumilast in Greater China (mainland China, Hong Kong, Macau, and Taiwan) and Southeast Asia (Indonesia, Singapore, The Philippines, Thailand, Myanmar, Brunei, Cambodia, Laos, Malaysia, and Vietnam). Huadong 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, and atopic dermatitis, and potentially additional dermatological conditions in the future.

“This collaboration provides Arcutis access to the second largest pharmaceutical market in the world, providing an unparalleled opportunity to help individuals in this region suffering from immune-mediated skin diseases, and provides meaningful non-dilutive capital for us. With Huadong’s deep dermatology and regional expertise, we are confident they are the ideal partner to develop and commercialize topical roflumilast for multiple dermatological indications in the Greater China and Southeast Asia markets,” said Frank Watanabe, President and Chief Executive Officer, Arcutis. “This collaboration provides further validation of topical roflumilast’s potential to be an effective and well-tolerated steroid-free treatment option for millions of people.”

“Arcutis is a leader in medical dermatology with a successful launch of topical roflumilast cream in plaque psoriasis and three additional successful Phase 3 programs completed in seborrheic dermatitis, atopic dermatitis, and scalp and body psoriasis in the United States. We are honored to partner with Arcutis to bring topical roflumilast to the Greater China and Southeast Asia markets and continue to make an impact for those suffering from immune-mediated skin diseases,” said Liang Lu, Chairman and CEO of Huadong Medicine.

Under the terms of the agreement, Arcutis will receive an upfront payment of $30 million, and an additional $64.25 million if certain regulatory and sales milestones are achieved. Arcutis is also eligible to receive tiered double-digit royalties.

Huadong will be responsible for development, manufacturing, and commercialization of roflumilast cream 0.3% and other topical roflumilast presentations in Greater China and Southeast Asia with the oversight of a joint steering committee comprised of individuals from both companies. Arcutis will continue to be responsible for the development and commercialization of ZORYVE in the United States and other geographies. The transaction is effective immediately upon the execution of the Collaboration and License Agreement.

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. Roflumilast foam is a once-daily foam formulation of roflumilast which the Company is developing for both seborrheic dermatitis and scalp and body psoriasis.

Roflumilast cream 0.3% (ZORYVE®) is approved by the Food and Drug Administration (FDA) for the topical treatment of plaque psoriasis in adults and adolescents.

About ZORYVE (roflumilast) Cream 0.3%
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
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 Prescribing Information.

About Arcutis
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is an early 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 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.

About Huadong Medicine

Huadong Medicine Co., Ltd. (SZ.000963) is a leading Chinese pharmaceutical company based in Hangzhou, China. Founded in 1993, Huadong Medicine has fully integrated R&D, manufacturing, distribution, sales, and marketing capabilities. Huadong Medicine's product portfolio and pipeline are specialized in oncology, immune-dermatology, nephrology, and diabetes. The company has 14,000 employees and one of the most extensive commercial coverage and marketing capabilities in China. 'Patient Centered, Science Driven' is Huadong Medicine's value. For additional information, please visit www.eastchinapharm.com/en.

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 topical roflumilast, as well as the commercial launch of ZORYVE in plaque psoriasis in the United States and other geographies. 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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