



## Arcutis and Padagis Agree to Stay Patent Lawsuit

April 2, 2025

WESTLAKE VILLAGE, Calif., April 02, 2025 (GLOBE NEWSWIRE) -- [Arcutis Biotherapeutics, Inc.](#) (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, is pleased to announce that Padagis Israel Pharmaceuticals Ltd., Padagis US LLC, and Padagis LLC (Padagis) have requested a stay to the ongoing patent litigation between Padagis and the Company, and the Company has agreed to enter a joint stipulation to stay the case, which was filed in the U.S. District Court for the District of Delaware on April 2, 2025. After the Court enters the joint stipulation, all calendared dates and trial for the patent litigation will be vacated.

As part of the joint stipulation agreement, Padagis is required to report to Arcutis any U.S. Food and Drug Administration (FDA) correspondence regarding their Abbreviated New Drug Application (ANDA) for their potential generic alternative to Arcutis' patented product, ZORYVE® (roflumilast) cream 0.3% for plaque psoriasis. In addition, the parties agreed to extend the 30-month Hatch-Waxman stay of regulatory approval by one day for every day the litigation is stayed as of March 24, 2025, such that in the event the litigation resumes in the future, Arcutis will still benefit from the entirety of the stay afforded to it under the Hatch-Waxman Act.

"This joint stipulation is a positive development for Arcutis that fully preserves our ability to assert our intellectual property while also preserving the Hatch-Waxman stay. As we have previously communicated, we maintain confidence in the strength of our broad patent portfolio that protects the innovative aspects of ZORYVE and in our legal position against Padagis. If and when the stay is lifted, we will continue to vigorously defend our intellectual property rights as appropriate, and to fight against any attempts by Padagis to infringe our patents," said Frank Watanabe, president and CEO, Arcutis. "Our focus is to continue to build upon the strong adoption of ZORYVE as a safe and effective therapy and alternative to steroids for three major inflammatory dermatoses and continue to deliver meaningful innovation to millions of individuals impacted by plaque psoriasis, seborrheic dermatitis and atopic dermatitis."

Patent protection for ZORYVE cream 0.3% extends until at least 2037. ZORYVE cream 0.3% is indicated for the topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 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](http://www.arcutis.com) or follow Arcutis on [LinkedIn](#), [Facebook](#), [Instagram](#) and [X](#).

### 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 ( $\geq 1\%$ ) 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 ( $\geq 1\%$ ) 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 ( $\geq 1\%$ ) 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

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. For example, 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 Arcutis' patent portfolio, regulatory processes and litigation and related proceedings, as well as adoption 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, 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 25, 2025, as well as any subsequent filings with the SEC. Any forward-looking statements that the company makes in this press release are made pursuant to the Private Securities Litigation Reform Act of 1995, as amended, and speak only as of the date of this press release. Except as required by law, we undertake no obligation to revise or update information herein to reflect events or circumstances in the future, even if new information becomes available.

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