



## Arcutis Announces Positive Long-Term Results of Roflumilast Cream 0.05% Show Durable and Improved Efficacy Over Time and Favorable Safety Profile in Treatment of Children Aged 2 to 5 with Mild to Moderate Atopic Dermatitis

August 28, 2024

- Long-term safety and tolerability profile consistent with pivotal data in atopic dermatitis (AD), with no new safety signals observed during 56 weeks of treatment
- Results from open-label extension study highlight that 71.9% of patients who rolled over from the roflumilast cream treatment arm in INTEGUMENT-PED achieved EASI-75 at Week 56
- Arcutis intends to submit a supplemental New Drug Application (sNDA) to the U.S. Food and Drug Administration (FDA) in the first quarter of 2025 for roflumilast cream 0.05%

WESTLAKE VILLAGE, Calif., Aug. 28, 2024 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced results from the INTEGUMENT-OLE long-term open-label study of once-daily roflumilast cream 0.05% demonstrating the durable efficacy and favorable safety profile of roflumilast cream 0.05% in the treatment of mild to moderate AD in children 2 to 5 years old. In the study, roflumilast cream was well-tolerated, with no new safety signals observed during treatment of up to 56 weeks in duration. Efficacy was not only maintained but improved over time, with 71.9% of participants who rolled over from the roflumilast cream 0.05% treatment arm in INTEGUMENT-PED achieving 75% improvement from baseline in Eczema Area and Severity Index (EASI-75) after 56 weeks.

"When choosing a therapy for very young children, health care providers and caregivers are looking for treatments that provide both rapid relief and are well-tolerated and suitable for long-term use," said Adelaide Hebert, MD, professor of dermatology and pediatrics at UTHealth Houston, and INTEGUMENT trial investigator. "These results build upon the findings from the Phase 3 trial of roflumilast cream 0.05% that demonstrated rapid efficacy within the first 4 weeks of treatment, and further showed long-term durable efficacy and tolerability of investigational roflumilast cream, with continued improvement over the course of the long-term study."

In the study, 53.8% of participants who rolled over from the roflumilast cream treatment arm in INTEGUMENT-PED achieved a validated Investigator Global Assessment-Atopic Dermatitis (vIGA-AD) success, defined as vIGA-AD value of 0 or 1 plus a 2-grade improvement from baseline, at 56 weeks.

The long-term study results reinforce the safety and tolerability profile of roflumilast cream 0.05% already seen in the 4-week pivotal INTEGUMENT-PED clinical trial, with no new safety signals observed up to 56 weeks. Overall incidence of adverse events was low, with most being mild to moderate in nature. The most frequently reported adverse events ( $\geq 3\%$ ) included: upper respiratory tract infection, nasopharyngitis, pyrexia, influenza, COVID-19, and otitis media. Overall, only 3.0% of trial participants discontinued the study due to adverse events.

"Roflumilast cream is uniquely formulated with the AD patient in mind, to deliver treatment without sensitizing excipients and irritants, which can often disrupt the skin barrier. We are excited by these results, which reinforce the strength of our ZORYVE product portfolio and specifically demonstrate the long-term efficacy, safety and tolerability profile of our once-daily roflumilast cream for the treatment of pediatric AD," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. "Based on these positive results, we are convinced that, if approved, roflumilast cream 0.05% can help provide immediate as well as long-term management of this burdensome skin condition, expanding the treatment population to children down to age 2."

Arcutis intends to submit a sNDA to the FDA in the first quarter of 2025 for roflumilast cream 0.05% for the treatment of AD in individuals ages 2-5 years. ZORYVE<sup>®</sup> (roflumilast) cream 0.15% is approved for the topical treatment of mild to moderate AD in adults and pediatric patients down to age 6.

### About INTEGUMENT-OLE

The "INterventional Trial Evaluating roflUMilast cream for the treatmENT of aTopic dermatitis Open Label Extension (INTEGUMENT-OLE) was a Phase 3, multicenter, open-label extension study of the long-term safety of roflumilast cream 0.15% in adults and children ages 6 years and older with AD and roflumilast cream 0.05% in children ages 2 to 5 years. A total of 562 individuals enrolled in the study after completing the INTEGUMENT-PED Phase 3 trial.

The study evaluated monotherapy with roflumilast cream 0.05% with no rescue treatment permitted. Beginning at Week 4 of INTEGUMENT-OLE, any participant who achieved vIGA-AD of '0-Clear' switched to twice weekly maintenance treatment. Participants were able to continue twice weekly maintenance dosing, as long as vIGA-AD remained either '0 -Clear' or '1-Almost Clear'. Participants resumed once-daily dosing if vIGA-AD reached  $\geq 2$ -Mild, and could also resume once-daily dosing if signs/symptoms of AD were not adequately controlled with maintenance therapy.

The primary objective of the study was to assess the long-term safety of roflumilast cream. Secondary endpoints included vIGA-AD score of 0 or 1 at each assessment, vIGA-AD success defined as vIGA-AD value of 0 or 1 plus a 2-grade improvement from baseline, and Eczema Area and Severity Index (EASI) score over time. The assessment of vIGA-AD Success and EASI-75 response, as reported here, references baseline of INTEGUMENT-PED.

### About Atopic Dermatitis

AD is the most common type of eczema, affecting approximately 9.6 million children and 16.5 million adults in the United States. AD is characterized by a defect in the skin barrier, which allows allergens and other irritants to enter the skin, leading to an immune reaction and inflammation. This reaction produces a red, itchy rash, most frequently occurring on the face, arms, and legs. The rash can cover significant areas of the body, in some

cases half of the body or more. AD typically begins in early childhood and is chronic. It persists into adolescence and even adulthood in some individuals. The rash causes significant pruritus (itching), which can lead to skin damage caused by scratching or rubbing. Since a large percentage of AD patients are very young children, safety is a particularly important consideration in treatment selection.

#### **About Roflumilast Cream**

Roflumilast cream is a next generation topical phosphodiesterase-4 (PDE4) inhibitor. 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 cream 0.3% (ZORYVE®) is approved by the FDA for the topical treatment of plaque psoriasis, including intertriginous areas, in patients 6 years of age and older. Roflumilast cream 0.15% (ZORYVE®) is approved by the U.S. Food and Drug Administration (FDA) for the topical treatment of mild to moderate atopic dermatitis, in patients 6 years of age and older. A lower dose, roflumilast cream 0.05%, was evaluated for children aged 2 to 5 years.

#### **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.

#### **IMPORTANT SAFETY INFORMATION**

ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

The most common adverse reactions (≥1%) for ZORYVE cream 0.3% 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%).

Please see full [Prescribing Information](#).

#### **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, AD, and alopecia areata. For more information, visit [www.arcutis.com](http://www.arcutis.com) or follow Arcutis on [LinkedIn](#), [Facebook](#), [Instagram](#), and [X](#).

#### **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 and timing for roflumilast cream to be approved by the FDA for the treatment of children ages 2 to 5 with AD, the potential to use roflumilast cream in those ages over a long period of time, or chronically, the potential to use roflumilast cream anywhere on the body, and the potential for roflumilast cream to advance the standard of care in AD and other inflammatory dermatological conditions. 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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