FDA Approves Arcutis' ZORYVE® (roflumilast) Cream 0.3% for Treatment of Psoriasis in Children Ages 6 to 11

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Expanded indication for ZORYVE provides new, steroid-free topical for children 6 to 11 with plaque psoriasis, including intertriginous psoriasis

WESTLAKE VILLAGE, Calif., Oct. 06, 2023 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (NASDAQ: ARQT), an early commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the U.S. Food and Drug Administration (FDA) has approved the supplemental new drug application (sNDA) to expand the indication of ZORYVE (roflumilast) cream 0.3% for the topical treatment of plaque psoriasis, including intertriginous areas, to children ages 6 to 11 years. ZORYVE, a once-daily, steroid-free cream that is effective, safe, and well tolerated, is designed to simplify management of plaque psoriasis.

"Young children with plaque psoriasis lack treatment options, which is why today's decision by the FDA represents a meaningful advancement for this pediatric population, their parents, and caregivers," said Patrick Burnett, MD, PhD, FAAD, chief medical officer at Arcutis. "ZORYVE has been shown to be safe, well tolerated, and effective; all critical factors for treating children with plaque psoriasis. We are excited to now be able to expand the availability of ZORYVE to children as young as 6 years old, offering them and their families an important new steroid-free treatment option to consider along with their healthcare providers."

As with adults and adolescents, plaque psoriasis is the most common form of psoriasis in children 6 to 11 years of age, and presents with very similar clinical features, including "plaques," or raised, red areas of skin covered with a silver or white layer of dead skin cells. Plaques in sensitive areas, where the skin may be thinner or more sensitive, pose specific treatment challenges.

"In children, psoriasis ranges from mild to severe, and more often appears on sensitive areas including the face and skin folds, compared to adults. Topical steroids are commonly recommended medications for the treatment of pediatric psoriasis. However, they come with safety and tolerability concerns related to long-term use. Steroid-free topical treatments that can be used on sensitive areas are especially needed for managing plaque psoriasis in younger children," said Adelaide A. Hebert, MD, professor and chief of pediatric dermatology at McGovern Medical School at UTHealth Houston and Children's Memorial Hermann. "In clinical studies with ZORYVE in the pediatric population, efficacy was consistent with the pivotal Phase 3 DERMIS-1 and DERMIS-2 trial results in adults. In addition, ZORYVE was shown to be safe and well tolerated, an important consideration for managing plaque psoriasis, especially in children."

ZORYVE is the only topical treatment for which efficacy in intertriginous areas (skin folds) was evaluated in the pivotal trials and the only product specifically indicated for use in these areas. A non-greasy, moisturizing cream that absorbs quickly and spreads easily, ZORYVE does not include sensitizing excipients or irritants such as propylene glycol, polyethylene glycol, isopropyl alcohol, ethanol, or fragrances.

"Psoriasis is the second most common inflammatory skin disease in children, and it can significantly affect the quality of life of the child, their family members, and caregivers," said Leah M. Howard, JD, president and CEO of the National Psoriasis Foundation. "We are told by the experts that advise us that there are numerous challenges when it comes to treating children, and finding the right treatment regimen can be difficult, which is why we are encouraged by the advancements being made to alleviate the burden of disease for this population."

The approval of the expanded indication is based on data from a 4-week Maximal Usage Systemic Exposure (MUSE) study in children ages 6 to 11 years with plaque psoriasis. Pharmacokinetic, safety, tolerability, and efficacy data from this study were generally consistent with data from the DERMIS-1 and DERMIS-2 pivotal Phase 3 trials in adults. Results from a second MUSE study, in children ages 2 to 5 years, as well as data from an ongoing open label extension study to assess the long-term safety of roflumilast cream 0.3% in individuals with plaque psoriasis 2 years of age and older (ARQ-151-306), will be the subject of a future FDA review.

A Media Snippet accompanying this announcement is available by clicking on the image or link below:

About Psoriasis
Psoriasis is a common, non-contagious, immune-mediated skin disease that affects approximately nine million people in the United States. The majority of individuals with psoriasis develop "plaques," or raised, red areas of skin covered with a silver or white layer of dead skin cells. The plaques' clinical presentation may have more grayish, purplish, or brownish tones in people with darker skin tones. Psoriatic plaques are often itchy and sometimes painful and can appear on any area of the body. Plaques in certain anatomical areas present unique treatment challenges, including the face, elbows and knees, scalp, and intertriginous areas (where two skin areas may touch or rub together), such as armpits, under the breasts, groin, and stomach folds.

About ZORYVE®
ZORYVE (roflumilast) cream 0.3% is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in 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%) 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%).

Please see full Prescribing Information.

ZORYVE is for topical use only and not for ophthalmic, oral, or intervaginal use.

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 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 for ZORYVE to simplify disease management for care of plaque psoriasis, including in children, the potential for roflumilast to gain an expanded approval for the treatment of children ages 2-5 years for plaque psoriasis, the potential of real-world use results of roflumilast cream, as well as the commercial launch of ZORYVE in plaque psoriasis. 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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