Study Showing Significant Improvements in Itch and Itch-Related Sleep Loss with Roflumilast Cream in Adults with Plaque Psoriasis Published in American Journal of Clinical Dermatology

November 28, 2022

- *Newly published phase 2b trial data show those treated with roflumilast cream had significantly greater improvements in itch compared to those treated with vehicle by Week 2 as assessed by the Worst Itch Numeric Rating Scale (WI-NRS) and Psoriasis Symptom Diary (PSD)*
- *Among a subset of participants with a baseline WI-NRS ≥6, significantly more individuals treated with roflumilast cream 0.3% than with vehicle achieved a ≥4-point improvement as early as Week 2*
- *Roflumilast-treated patients also experienced significantly greater improvements in itch-related sleep loss Weeks 6 through 12*

WESTLAKE VILLAGE, Calif., Nov. 28, 2022 (GLOBE NEWSWIRE) -- Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), an early commercial-stage company focused on developing meaningful innovations in immuno-dermatology, today announced the publication of positive patient-reported outcome itch data from its Phase 2b study evaluating once-daily roflumilast cream (0.3% and 0.15%) in adults with chronic plaque psoriasis. The study, which was published online in the *American Journal of Clinical Dermatology* shows that those treated with roflumilast cream 0.3% experienced significantly greater improvements in WI-NRS as well as severity and bother of itch (as measured by PSD) by the earliest timepoint measured, Week 2, and itch-related sleep loss from Weeks 6 through 12, than those treated with vehicle. Roflumilast is a selective, highly potent phosphodiesterase-4 inhibitor (PDE4), with greater affinity for PDE4 and approximately 25- to >300-fold more potency than other FDA-approved PDE4 inhibitors.

“As a clinician and researcher, I see first-hand how itch can negatively affect people with chronic plaque psoriasis, in particular on the quality and quantity of their sleep,” said Linda Stein Gold, MD, Director of Dermatology Clinical Research and Division Head of Dermatology at Henry Ford Health System and lead author of the paper. “These data show that roflumilast cream is an important non-steroidal treatment option that is able to address this burdensome symptom of plaque psoriasis, and provide those struggling with itch much-needed, and rapid relief, as early as two weeks.”

In the parallel-group, double-blind, vehicle-controlled phase 2b clinical trial, 331 subjects ranging from ages 18 to 89 years were randomized to roflumilast 0.3% cream, roflumilast 0.15% cream or vehicle in a 1:1:1 ratio. Roflumilast cream or vehicle was applied once daily to all psoriasis lesions for 12 weeks.

Improvement in WI-NRS was greater in individuals treated with roflumilast cream in both arms compared to vehicle beginning at Week 2 ($p \leq 0.002$), the first timepoint measured. Among a subgroup of participants with a baseline WI-NRS $\geq$6, significantly more of those treated with roflumilast 0.3% achieved an improvement of ≥4 compared to vehicle by Week 2 ($p \leq 0.034$).

Those treated with roflumilast cream in both arms reported greater improvements in severity of itch and bother of itch, as measured by PSD, compared to vehicle at Weeks 2 to 12 ($p \leq 0.012$ and $p \leq 0.010$, respectively). Additionally, both roflumilast-treated groups experienced similar improvements in itch-related sleep loss as measured by itch-related sleep loss NRS, which was greater than the vehicle-treated group beginning at Week 6 ($p \leq 0.022$). Improvement on the Dermatology Life Quality Index (DLQI) Score was observed at Week 6 for those treated with roflumilast cream 0.3% compared to those treated with vehicle ($p = 0.045$) and for both roflumilast-treated groups at Week 12.

“These findings not only help us to better understand the role of roflumilast cream in addressing the often-challenging symptom of itch in individuals with chronic plaque psoriasis, but also shed light on how people living with the disease may experience itch, regardless of their disease severity, and its impact on their lives,” said Patrick Burnett MD, PhD, FAAD, Chief Medical Officer at Arcutis. “We are pleased to share these data with the medical dermatology community through publication in this excellent journal. We believe the ability to rapidly reduce itch, coupled with the safety and tolerability of now approved ZORYVE roflumilast cream is a key differentiator.”

In July 2022, ZORYVE® (roflumilast) cream 0.3% was approved for the topical use in adults and adolescents with mild to severe plaque psoriasis, including intertriginous psoriasis.

To learn more about the data, view the full text of “Effect of Roflumilast Cream (ARQ-151) on Itch and Itch-Related Sleep Loss in Adults with Chronic Plaque Psoriasis: Patient-Reported Itch Outcomes of a Phase 2b Trial” here: https://link.springer.com/article/10.1007/s40257-022-00739-3.

About ZORYVE (roflumilast) Cream 0.3%
ZORYVE (roflumilast) cream 0.3% is a next generation topical inhibitor of phosphodiesterase-4 (PDE4) and the first topical PDE4 inhibitor to be approved by the FDA for adults and adolescents with plaque psoriasis, including intertriginous psoriasis.

INDICATION
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 a 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 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 psoriasis, atopic dermatitis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn, Facebook, and Twitter.

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 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 the U.S. Securities and Exchange Commission (SEC) on February 22, 2022, as amended, 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.

Contacts:
Media
Amanda Sheldon, Head of Corporate Communications
asheldon@arcutis.com

Investors
Eric McIntyre, Head of Investor Relations
emcintyre@arcutis.com