

# NPF Expands Seal of Recognition to FDAapproved Treatments and Awards its First to Arcutis' ZORYVE® (roflumilast)

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The NPF Seal of Recognition highlights products that prove a commitment to being safe and non-irritating for people with psoriasis or psoriatic arthritis.

- ☐ NPF has expanded its Seal of Recognition to include FDA approved prescription drugs to better represent the full toolbox of options available for people with psoriatic disease
- ☐ Recognition underscores ZORYVE's non-irritating use, even on hard-to-treat areas
- ☐ ZORYVE is the first and only FDA-approved branded topical in foam and cream options for plaque psoriasis treatment
- ☐ Psoriasis impacts more than 8 million people in the United States

National Psoriasis Foundation (NPF), the leading advocacy, education, and research groups supporting people with psoriatic disease, and Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), a commercial-stage biopharmaceutical company focused on developing meaningful innovations in immuno-dermatology, today announced the awarding of the NPF's Seal of Recognition to Arcutis' ZORYVE® (roflumilast) cream 0.3% and ZORYVE® (roflumilast) topical foam 0.3%, both FDA approved for the treatment of plaque psoriasis. ZORYVE is the first FDA-approved product to receive the Seal of Recognition, which highlights products that have been created to be non-irritating and safe for people with psoriasis.

"The NPF Seal of Recognition is awarded to products that meet our rigorous standards for people living with psoriasis or psoriatic arthritis," said Leah M. Howard, J.D., president and CEO of the NPF. "We are pleased to expand our directory beyond over-the-counter items to recognize FDA-approved treatments like this one. It is great for our community to have multiple formulations that are suitable for sensitive and hard-to-treat areas. This reflects real progress in addressing the daily needs of people with psoriasis."

NPF's Seal of Recognition helps people with psoriasis and psoriatic arthritis find products that are safe and non-irritating for skin and joints. The program was launched in February 2012 and has grown over time, with NPF now adding new products regularly. The decision to expand the directory to include FDA approved products helps health care providers and people with the disease to see the full array of options for addressing psoriatic disease and its impactful symptoms.

"It is a tremendous honor that ZORYVE is the first FDA-approved product to receive the NPF Seal of Recognition. This is a testament to the dedication of our research, development, and technical operations teams to develop advanced targeted topical therapies," said Frank Watanabe, president and CEO of Arcutis. "Individuals living with psoriasis want steroid-free treatments that are safe and effective for long-term use, as well as convenient and versatile. With cream and foam formulations, ZORYVE offers individuals with psoriasis and their physicians a choice of their preferred formulation of ZORYVE, each providing powerful, long-term relief of plaques and itch anywhere on the body—including thin-skinned and hair-bearing areas—with no limitation on duration of use. This recognition reinforces our commitment to developing innovative therapies that meet the real-world needs of people with chronic inflammatory skin diseases."

For more information about the NPF Seal of Recognition, please visit <u>psoriasis.org/seal-of-recognition-program</u>.

For more information on ZORYVE, including prescribing information, please visit zoryve.com.

## **About Plaque Psoriasis**

Plaque psoriasis is the most common form of psoriasis, a chronic, systemic disease associated with inflammation throughout the body. Psoriasis affects more than 8 million people in the U.S. Symptoms include itch, scaling, redness, and flaking. On darker skin tones, plaques may appear more grayish, purplish, or brown. Psoriasis can appear anywhere on the body, including the knees, elbows, torso and thin-skinned areas like the face, genitals and intertriginous areas, which are areas where skin touches skin, such as the armpits, under the breasts, stomach folds, between the buttocks, and in the groin area. In addition, scalp psoriasis sometimes extends to the forehead, back of the neck, or behind or inside the ears. Scalp psoriasis can also be associated with hair loss, likely due to damage to the hair from excessive scratching, rubbing, or combing of the affected area.

# About ZORYVE (roflumilast)

ZORYVE is the first and only branded topical therapy for three major inflammatory dermatoses - including atopic dermatitis, seborrheic dermatitis, and plaque psoriasis. ZORYVE is a next generation topical 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 FDA for the topical treatment of mild to moderate atopic dermatitis in patients 6 years of age and older. In 2024, ZORYVE cream 0.15% was awarded Glamour's Beauty and Wellness Award for "Eczema Product." ZORYVE (roflumilast) topical foam, 0.3%, is uniquely formulated for use anywhere on the body, including hair-bearing areas, and is indicated for treatment of plaque psoriasis of the scalp and body in patients 12 years of age and older, as well as seborrheic dermatitis in patients 9 years of age and older.

#### **INDICATIONS**

ZORYVE topical foam, 0.3%, is indicated for the treatment of plaque psoriasis of the scalp and body in adult and pediatric patients 12 years of age and older.

ZORYVE topical foam, 0.3%, is indicated for the treatment of seborrheic dermatitis in adult and pediatric patients 9 years of age and older.

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).

Flammability: The propellants in ZORYVE foam are flammable. Avoid fire, flame, and smoking during and immediately following application.

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for plaque psoriasis include headache (3.1%), diarrhea (2.5%), nausea (1.7%), and nasopharyngitis (1.3%).

The most common adverse reactions (≥1%) for ZORYVE foam 0.3% for seborrheic dermatitis include nasopharyngitis (1.5%), nausea (1.3%), and headache (1.1%).

The most common adverse reactions (≥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%).

Please see <u>full Prescribing Information for ZORYVE cream</u> and <u>full Prescribing Information for ZORYVE foam</u>.

### About the National Psoriasis Foundation

The National Psoriasis Foundation is the leading nonprofit representing individuals with psoriasis and psoriatic arthritis. The mission of NPF is to drive efforts to cure psoriatic disease and improve the lives of more than 8 million individuals in the United States affected by this chronic immune-mediated disease. Learn more at psoriasis.org.

#### **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 of advanced targeted topicals approved to treat three major inflammatory skin diseases. Arcutis' unique dermatology development platform coupled with our dermatology expertise allows us to invent differentiated therapies against biologically validated targets, and has produced a robust pipeline with multiple follow-on clinical programs for a range of inflammatory dermatological conditions including atopic dermatitis and alopecia areata. For more information, visit <a href="https://www.arcutis.com">www.arcutis.com</a> or follow Arcutis on LinkedIn, Facebook, Instagram, and X.

## 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 the potential real-world use results of ZORYVE cream and ZORYVE foam in plaque psoriasis patients and the potential for ZORYVE to advance the standard of care in plaque psoriasis, atopic dermatitis and seborrheic dermatitis. 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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