# Arcutis Advances Science of Psoriasis Drug Development with New Precision Method for Measuring Mild-to-Moderate Psoriasis

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- The majority of patients with psoriasis have mild or moderate levels of disease
- The new method, PASI-high discrimination (PASI-HD), is designed for use in clinical trials evaluating novel topical treatment options for psoriasis
- Details of new approach published in *Dermatology and Therapy*

WESTLAKE VILLAGE, Calif., July 21, 2021 (GLOBE NEWSWIRE) -- In order to address a major limitation of today's most widely used method for gauging severity of plaque psoriasis (the PASI scale), Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT), in conjunction with leading psoriasis experts, has developed a revised scale that offers greater precision for measuring disease extent and therapeutic effects in patients with mild-to-moderate disease. Arcutis, a late-stage biopharmaceutical company that champions meaningful innovation to address immune-mediated dermatological diseases and conditions, shared details of the new approach in the peer-reviewed scientific journal *Dermatology and Therapy*.

"The majority of people affected by plaque psoriasis experience mild or moderate disease, yet clinicians lack the best possible tools to provide an accurate measurement of severity for those individuals," said Robert Higham, MPAS, PA-C, Executive Director of Clinical Development for Arcutis and one of the authors of the article. "As we work toward bringing topical treatment innovations for psoriasis to dermatologists and patients, we believe innovations are likewise needed to improve the tools and methods to properly diagnose and track all levels of disease and treatment effects."

The article notes that disease severity is an essential outcome measure in clinical trials of new treatments for plaque psoriasis. However, the most common clinical measure to assess disease severity—the Psoriasis Area and Severity Index (PASI)—is geared toward more-severe levels of disease. To determine a PASI score, the area of body region affected by psoriasis is estimated and given a number, but for body areas with less than 10 percent of disease, a non-granular score of 1 is applied regardless of the actual extent of disease, masking any changes in disease extent between 0 and 9 percent.

To address this shortcoming, Arcutis has introduced a key modification to PASI that more accurately measures severity and evaluates treatment effectiveness for areas of the body with mild-to-moderate levels of disease. The new method, PASI-high discrimination (PASI-HD), is designed to be used in clinical trials among patients for whom the areas of affected body surface within the anatomical regions measured by PASI are less than 10 percent.

"Other alternatives to the PASI have been proposed in the past, but no other option preserves the anatomical component of the index by assessing the severity and percentage of area affected in the four body regions: head and neck, upper extremities, trunk, and lower extremities," said co-author Kim Papp, M.D., Ph.D., a Fellow of the Royal College of Physicians of Canada and Founder and President of Probity Medical Research Inc. Papp, a scientific advisor for Arcutis, also co-authored the journal article.

In addition, PASI-HD more precisely captures disease flaring from and within areas with less than 10 percent of disease involvement.

"Even mild or moderate psoriasis significantly impacts quality of life, and deserves focused attention from the medical dermatology community," said Patrick Burnett, M.D., Ph.D., FAAD, Chief Medical Officer of Arcutis. "As part of our mission to revitalize the standard of care for dermatological diseases, we believe it is necessary to remove the challenges that have traditionally hampered innovation for patients with skin diseases."

In addition to Higham and Papp, authors of the article include colleagues at Arcutis and leading experts in the field of medical dermatology:

- Mark Lebwohl, M.D., Professor and Chair of the Kimberly and Eric J. Waldman Department of Dermatology of the Icahn School of Medicine, Mount Sinai and Arcutis scientific advisor
- Leon Kircik, M.D., Clinical Professor of Dermatology, Icahn School of Medicine, Mount Sinai, and Medical Director of DermResearch, PLLC, Physicians Skin Care, PLLC, and Skin Sciences
- David Pariser, M.D., Senior Physician at Pariser Dermatology Specialists
- Bruce Strober, M.D., Ph.D., Clinical Professor of Dermatology, Yale School of Medicine and Co-Founder of Central Connecticut Dermatology
- Gerald Krueger, M.D., Dermatologist at University of Utah

**About Arcutis**
Arcutis Biotherapeutics, Inc. (Nasdaq: ARQT) is a medical dermatology company that champions meaningful innovation to address the urgent needs of patients 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 seven clinical programs for a range of inflammatory dermatological conditions, with our first NDA submission anticipated by the end of 2021 and three more Phase 3 clinical data readouts anticipated over the next 18 months. The company's lead product candidate, topical roflumilast, has the potential to advance the standard of care for plaque psoriasis, atopic dermatitis, scalp psoriasis, and seborrheic dermatitis. For more information, visit www.arcutis.com or follow Arcutis on LinkedIn and Twitter.

**Forward-Looking Statements**
This press release contains "forward-looking" statements, including, among others, statements regarding the potential for roflumilast to revolutionize

the standard of care in plaque psoriasis and other inflammatory dermatological conditions. These statements involve 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 and you should not place undue reliance on our forward-looking statements. Risks and uncertainties that may cause our actual results to differ include risks inherent in the clinical development process and regulatory approval process, the timing of regulatory filings, and our ability to defend our intellectual property. For a further description of the risks and uncertainties applicable to our business, see the "Risk Factors" section of our Form 10-K filed with U.S. Securities and Exchange Commission (SEC) on February 16, 2021, as well as any subsequent filings with the SEC. 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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