Palvella Therapeutics Announces Scientific Publication in Clinical and Experimental Dermatology Highlighting a Systematic Review of Real-World Statin Evidence and Persistent Treatment Gaps Resulting from the Lack of FDA-Approved Therapies in Porokeratosis

February 2, 2026

Publication includes a systematic review of 24 studies describing off-label cutaneous application of statins in porokeratosis

Preliminary case reports suggesting clinical benefit underscore unmet need for development of a standardized, FDA-approved statin therapy evaluated in rigorous, well-designed clinical trials

WAYNE, Pa., Feb. 02, 2026 (GLOBE NEWSWIRE) -- (Nasdaq: PVLA) **Palvella Therapeutics, Inc.** (Palvella or "the Company"), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare skin diseases and vascular malformations for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, today announced the publication of a systematic review in *Clinical and Experimental Dermatology* which synthesizes available published clinical evidence on off-label statin use for cutaneous application in porokeratosis. The systematic review supports the scientific rationale and clinical potential for developing Palvella's QTORIN™ pitavastatin for the treatment of disseminated superficial actinic porokeratosis (DSAP), currently anticipated to enter Phase 2 development in the second half of 2026.

"Porokeratosis is a serious, progressive genetic skin disease that carries a meaningful risk of malignant transformation, particularly in patients with DSAP," said Maria Gnarra Buethe, MD, PhD, FAAD, Pediatric Dermatology Director at the University of California, Irvine, and Division Chief of Dermatology at Rady Children's Hospital of Orange County. "Advances in our understanding of porokeratosis have identified mutations in the mevalonate pathway as central drivers of disease pathogenesis. While systemic statins have not demonstrated clinical benefit—likely due to limited skin bioavailability—this systematic review underscores the mechanistic rationale and emerging clinical evidence supporting topical application of statins in porokeratosis as a potential targeted therapeutic approach for a condition with no FDA-approved treatments."

Clinical and Experimental Dermatology is a peer-reviewed journal published by Oxford University Press on behalf of the British Association of Dermatologists that provides clinically relevant research, reviews, case reports, and continuing professional development content to advance the understanding and management of skin disease worldwide. The publication, titled "Topical Statins in the Treatment of Porokeratosis: A Systematic Review," reviews 24 studies comprising 95 patients with porokeratosis treated via topical application of statins originally developed for systemic use, including atorvastatin, fluvastatin, lovastatin, rosuvastatin, and simvastatin. Dr. Maria Gnarra Buethe, Lihi Atzmony Maoz, MD, an Assistant Professor at the Yale School of Medicine's Department of Dermatology, and Jeff Martini, PhD, Chief Scientific Officer of Palvella, served as authors on the publication. Key findings from the review article include:

- Recent genetic studies have identified loss-of-function mutations in the mevalonate metabolic pathway as a major driver of porokeratosis pathogenesis, prompting real-world, off-label use of statins designed to inhibit HMG-CoA reductase, a key enzyme in the mevalonate pathway, in porokeratosis.
- The majority of patients in the systematic review experienced at least partial clinical benefit, with symptom relief and reductions in lesion size observed across a broad age range (2 to 85 years).
- The need for controlled clinical trials using standardized, optimized statin formulations and standardized endpoints to robustly evaluate safety and efficacy.

"There is a significant unmet need in porokeratosis, with no FDA-approved therapies and a high burden of disease characterized by numerous expanding lesions that do not spontaneously regress, which significantly impact quality-of-life," said Jeff Martini, Ph.D., Chief Scientific Officer of Palvella. "This systematic review highlights a potentially important role for QTORIN™ pitavastatin in porokeratosis. It also further validates Palvella's approach to addressing DSAP, the most common subtype of the disease, which affects an estimated more than 50,000 diagnosed patients in the U.S., with QTORIN™ pitavastatin, if approved."

About Palvella Therapeutics

Founded and led by rare disease drug development veterans, Palvella Therapeutics, Inc. (Nasdaq: PVLA) is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare skin diseases and vascular malformations for which there are no FDA-approved therapies. Palvella is developing a broad

pipeline of product candidates based on its patented QTORIN™ platform, with an initial focus on serious, rare skin diseases, many of which are lifelong in nature. Palvella's lead product candidate, QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin), is currently being developed for the treatment of microcystic lymphatic malformations, cutaneous venous malformations, and clinically significant angiokeratomas. Palvella's second product candidate, QTORIN™ pitavastatin, is currently being developed for the topical treatment of disseminated superficial actinic porokeratosis. For more information, please visit www.palvellatx.com or follow Palvella on LinkedIn or X (formerly known as Twitter).

QTORIN™ rapamycin and QTORIN™ pitavastatin are for investigational use only and neither has been approved by the FDA o by any other regulatory agency for any indication.

Forward-Looking Statements

This press release contains forward-looking statements (including within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended (Securities Act)). These statements may discuss goals, intentions, and expectations as to future plans, trends, events, results of operations or financial condition, or otherwise, based on current beliefs of the management of Palvella, as well as assumptions made by, and information currently available to, the management of Palvella. Forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "may," "will," "should," "would," "expect," "anticipate," "plan," "likely," "believe," "estimate," "project," "intend," and other similar expressions or the negative or plural of these words, or other similar expressions that are predictions or indicate future events or prospects, although not all forward-looking statements contain these words. Statements that are not historical facts are forward-looking statements. Forward-looking statements include, but are not limited to, statements regarding the expected timing of the presentation of data from ongoing clinical trials, including the TOIVA study, Palvella's clinical development plans and related anticipated development milestones, Palvella's plans to pursue Breakthrough Therapy Designation, Palvella's plans to meet with regulatory authorities, Palvella's cash, financial resources and expected runway, Palvella's expectations regarding its programs, including QTORIN™ rapamycin and QTORIN™ pitavastatin, and its research-stage opportunities, including its expected therapeutic potential and market opportunity. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties and are not guarantees of future performance. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors, including, without limitation: the ability to raise additional capital to finance operations; the ability to advance product candidates through preclinical and clinical development; the ability to obtain regulatory approval for, and ultimately commercialize, Palvella's product candidates, including QTORIN™ rapamycin and QTORIN™ pitavastatin; the outcome of early clinical trials for Palvella's product candidates, including the ability of those trials to satisfy relevant governmental or regulatory requirements; the fact that data and results from clinical studies may not necessarily be indicative of future results; Palvella's limited experience in designing clinical trials and lack of experience in conducting clinical trials; the ability to identify and pivot to other programs, product candidates, or indications that may be more profitable or successful than Palvella's current product candidates; the substantial competition Palvella faces in discovering, developing, or commercializing products; the negative impacts of global events on operations, including ongoing and planned clinical trials and ongoing and planned preclinical studies; the ability to attract, hire, and retain skilled executive officers and employees; the ability of Palvella to protect its intellectual property and proprietary technologies; reliance on third parties, contract manufacturers, and contract research organizations; and the risks and uncertainties described in the filings made by Palvella with the Securities and Exchange Commission (SEC), including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the SEC and available at www.sec.gov. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties that Palvella may face. Except as required by applicable law, Palvella does not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. This press release contains hyperlinks to information that is not deemed to be incorporated by reference into this press release.

Contact Information

Investors
Wesley H. Kaupinen
Founder and CEO, Palvella Therapeutics
wes.kaupinen@palvellatx.com

Media
Marcy Nanus
Managing Partner, Trilon Advisors LLC
mnanus@trilonadvisors.com