Palvella Therapeutics Announces New QTORIN™ Product Candidate, QTORIN™ Pitavastatin, for the Treatment of Disseminated Superficial Actinic Porokeratosis (DSAP), a Rare, Chronic, and Pre-Cancerous Genetic Skin Disease with No FDA-Approved Therapies

November 5, 2025

DSAP is a premalignant, progressive disease characterized by numerous expanding lesions which significantly impact quality-of-life; no FDA-approved therapies exist for the estimated more than 50,000 diagnosed U.S. patients

QTORIN™ pitavastatin has the potential to be the first pathogenesis-directed therapy designed to directly inhibit the mevalonate pathway, the causal driver of DSAP, in the pathogenic skin tissue

Company plans to initiate a Phase 2 trial evaluating QTORIN™ pitavastatin for DSAP in the second half of 2026

Company to host webcast conference call today, November 5, 2025 at 8:30am ET

WAYNE, Pa., Nov. 05, 2025 (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 for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, today announced a new product candidate, QTORIN™ pitavastatin, for the treatment of disseminated superficial actinic porokeratosis (DSAP). QTORIN™ pitavastatin was developed leveraging QTORIN™, the company's patented platform for reproducibly generating novel, topical product candidates for the targeted treatment of serious, rare skin diseases.

DSAP is a genetic skin disease that results from mutations in the mevalonate pathway, leading to the accumulation of toxic intermediates. Clinically, DSAP presents as persistent, often extensive lesions that enlarge and increase in size, number, and extent over time. These lesions cause chronic loss of skin integrity, which can severely impact quality-of-life. DSAP is premalignant, with potential transformation to squamous cell carcinoma, particularly in long-standing or widespread cases. Spontaneous regression is extremely rare, and no FDA-approved therapies currently exist for the estimated more than 50,000 diagnosed patients in the United States.

"QTORIN™ pitavastatin has the potential to be the first pathogenesis-directed therapy for the treatment of DSAP, a serious, rare skin disease which currently has no FDA-approved therapies,” said Wes Kaupinen, Founder and Chief Executive Officer. “Recent breakthrough scientific discoveries further characterizing the genetics and biology of DSAP, as well as published case studies on the use of off-label topical statins, provide strong scientific rationale for advancing the development of QTORIN™ pitavastatin. With its superior potency relative to other mevalonate pathway inhibitors, pitavastatin represents a next-generation statin ideally suited for QTORIN™ development in DSAP.”

Palvella plans to meet with the FDA in the first half of 2026 to discuss the proposed design of a Phase 2 clinical trial evaluating QTORIN™ pitavastatin in subjects with disseminated superficial actinic porokeratosis. Trial initiation is anticipated in the second half of 2026.

Webcast Conference Call Details

Palvella will host a conference call and live audiovisual webcast to discuss its new clinical candidate QTORIN™ pitavastatin at 8:30 a.m. ET today. The conference call format will be presentation only. To access the live webcast of the call with slides, please click here or visit the “Events & Presentations” section of Palvella’s website. A replay of the webcast will be available approximately 2 hours after the conclusion of the call and archived for 90 days under the “Events & Presentations” section of the Company's website at www.palvellatx.com.

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 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 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 or cleared by the FDA or 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, Palvella's clinical development plans and related anticipated development milestones, 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.

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