# Palvella Therapeutics Announces QTORIN™ Docetaxel, a New QTORIN™ Program for the Treatment of Extramammary Paget's Disease (EMPD)

November 19, 2026

*EMPD is a serious, rare, and life-threatening genital and perianal skin cancer*

*QTORIN™ docetaxel builds on human clinical evidence of I.V. docetaxel in EMPD, with the potential to shift the treatment paradigm to first-line, localized topical therapy*

*QTORIN™ docetaxel has the potential to be the first FDA-approved therapy for the estimated more than 10,000 U.S. patients living with EMPD*

*Palvella has initiated IND-enabling activities and plans to commence a Phase 2 study following regulatory interactions*

*Company to host webcast conference call today, November 19, 2026, at 8:30 a.m. ET*

WAYNE, Pa., Nov. 19, 2026 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc. (Nasdaq: PVLA) ("Palvella" or the "Company"), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies for serious, rare skin diseases and vascular anomalies for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, today announced QTORIN™ docetaxel, a new QTORIN™ program for the treatment of Extramammary Paget's Disease (EMPD). QTORIN™ docetaxel is the Company's third product candidate developed from QTORIN™, its proprietary platform for reproducibly generating novel, topical product candidates for the treatment of serious, rare skin diseases and vascular anomalies.

EMPD is a serious, rare, and life-threatening cancer that originates in the skin, most commonly on the vulva, scrotum, or perianal region. Patients live with red, scaly plaques that can itch, burn, weep, and ulcerate. EMPD can invade deeper tissue and progress to metastatic disease. Patients often undergo multiple disfiguring surgeries that require skin grafts, and EMPD has been documented to have high recurrence rates after treatment. There are no FDA-approved therapies for EMPD, which affects an estimated more than 10,000 patients in the U.S.

"Our objective is to bring meaningful innovation, and ultimately the first FDA-approved therapy, to the EMPD community," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "Today, patients with EMPD often face repeated, disfiguring surgeries and high rates of disease recurrence. QTORIN™ docetaxel builds on human clinical evidence of I.V. docetaxel in metastatic EMPD, with the potential to transform the treatment paradigm to first-line, localized topical therapy. EMPD has the hallmark characteristics of an opportunity where Palvella can make a significant impact: a serious, rare skin disease with no FDA-approved therapies, a compelling scientific rationale, and a clear path toward potentially delivering the first FDA-approved therapy."

Palvella has initiated IND-enabling activities for QTORIN™ docetaxel, with plans to meet with the FDA in the first half of 2027 and subsequently initiate a Phase 2 study.

**Webcast Conference Call Details**

Palvella will host a conference call and live audiovisual webcast today at 8:30 a.m. ET to discuss its new program, QTORIN™ docetaxel. The call will be presentation-only. To access the live webcast with slides, please click here or visit the "Events & Presentations" section of the Company's website at www.palvellatx.com. A replay will be available approximately two hours after the call and archived on the website for 90 days.

**About Palvella Therapeutics**

Founded and led by rare disease biotech veterans, Palvella Therapeutics, Inc. (Nasdaq: PVLA) is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients living with serious, rare skin diseases and vascular anomalies 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 and vascular anomalies, 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. Palvella's third product candidate, QTORIN™ docetaxel, is currently being developed for the treatment of Extramammary Paget's Disease. For more information, please

visit www.palvellatx.com or follow Palvella on LinkedIn or X (formerly known as Twitter).

QTORIN™ rapamycin, QTORIN™ pitavastatin, and QTORIN™ docetaxel are for investigational use only and have not bee approved 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 clinical trials, Palvella's clinical development plans and related anticipated development milestones and anticipated timing of regulatory submissions, Palvella's plans to meet with regulatory authorities, including its planned meeting with the FDA regarding QTORIN™ docetaxel, the anticipated timing of initiation of a Phase 2 study of QTORIN™ docetaxel, , Palvella's expectations regarding its programs, including QTORIN™ docetaxel, 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 make regulatory submissions on anticipated timelines; the ability to obtain regulatory approval for, and ultimately commercialize, Palvella's product candidates, including QTORIN™ docetaxel; 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; 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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