



Palvella Therapeutics Announces Three Poster Presentations Highlighting New Data in Microcystic Lymphatic Malformations and DSAP at Fall Clinical Dermatology 2026

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Phase 3 SELVA Patient, Caregiver, and Clinician Interviews Highlight Meaningful Clinical Improvements and High Treatment Satisfaction With QTORIN™ Rapamycin

SELVA Maximal-Use Pharmacokinetic Substudy Demonstrates Low and Stable Systemic Rapamycin Exposure Over 24 Hours

Comprehensive Real-World Claims Analysis Identifies an Estimated 154,986 Patients Diagnosed With DSAP in the U.S.

WAYNE, Pa., Oct. 12, 2026 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc. (Palvella or the "Company") (Nasdaq: PVLA), 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 three poster presentations at the 26th Annual Fall Clinical Dermatology Conference. Copies of the posters are available [here](#) in the "Publications & Presentations" section of Palvella's website. The findings are expected to be submitted for publication in peer-reviewed journals.

The presentations highlight findings from patient, caregiver, and clinician interviews conducted as part of the Phase 3 SELVA study evaluating QTORIN™ rapamycin in microcystic lymphatic malformations (microcystic LMs); systemic exposure data from the SELVA maximal-use pharmacokinetic substudy; and a real-world claims analysis estimating the U.S. population diagnosed with disseminated superficial actinic porokeratosis (DSAP).

SELVA Participant Interviews Highlight Clinical Benefits and High Treatment Satisfaction with QTORIN™ Rapamycin for Microcystic LMs

The poster, titled "Patient- and Clinician-Reported Meaningfulness of Treatment-Related Change Following Investigational Sirolimus Topical Gel 3.9% in Microcystic Lymphatic Malformations: Qualitative Findings From the Phase 3 SELVA Trial Show Clinical Benefit and High Treatment Satisfaction," presents an embedded qualitative interview study that captured patient, caregiver, and clinician perspectives to contextualize clinical efficacy endpoints and evaluate treatment satisfaction.

At Week 24, all exit-interview participants reported improvement in at least one symptom of microcystic LMs, most commonly bleeding/leaking and color, and described these improvements as meaningful. Patient, caregiver, and clinician interviews revealed consistent improvements in key manifestations of microcystic LMs. All participants who completed the TSQM-9 reported treatment satisfaction, and 98% of SELVA participants who completed the 24-week Efficacy Evaluation Period elected to continue treatment in the Treatment Extension Period.

These findings were consistent with the positive clinical efficacy results from the Phase 3 SELVA study. Among participants who completed the 24-week Efficacy Evaluation Period, 95% demonstrated improvement on the study's primary efficacy endpoint, the Microcystic Lymphatic Malformation Investigator Global Assessment (mLM-IGA), including 86% who were rated as "Much Improved" or "Very Much Improved."

SELVA Maximal-Use Pharmacokinetic Substudy Demonstrates Low and Stable Systemic Rapamycin Exposure Over 24 Hours

The poster, titled "Systemic Pharmacokinetics of Investigational Sirolimus Topical Gel 3.9% Under Maximal Use Conditions in Microcystic Lymphatic Malformations: Results from the Phase 3 SELVA PK-MuST," presents data characterizing systemic rapamycin exposure under maximal intended clinical use conditions across a broad range of ages, disease severities, and treated lesion areas. It also compares these findings with published pharmacokinetic data for oral rapamycin.

In a maximal-use pharmacokinetic substudy involving 24 participants with microcystic LMs, mean systemic rapamycin exposure with QTORIN™ rapamycin was at least 40-fold lower than reported exposure with oral sirolimus. Systemic concentrations remained low and stable over 24 hours, with exposure consistent across age groups, treated lesion areas, disease severities, and administered doses. The substantially lower mean systemic exposure observed with QTORIN™ rapamycin compared with reported oral sirolimus exposure potentially supports a favorable systemic exposure profile.

In August 2026, Palvella completed the rolling submission of its New Drug Application (NDA) to the FDA for QTORIN™ rapamycin for the treatment of microcystic LMs.

Real-World Claims Analysis Identifies an Estimated 154,986 Diagnosed DSAP Patients in the U.S.

The poster, titled “Real world analysis of paid claims database reveals that disseminated superficial actinic porokeratosis (DSAP) is a large orphan disease,” presents findings from an eight-year analysis of U.S. paid claims data from Komodo Health, designed to estimate the number of patients diagnosed with DSAP in the U.S. and characterize their demographics, associated comorbidities, and treatment patterns.

The analysis identified an estimated 154,986 U.S. patients diagnosed with DSAP during 2018–2025. The methodology required at least two occurrences of ICD-10 diagnosis code L56.5 and adjustments for age-specific population capture rates. These findings represent the first real-world, claims-based characterization of the diagnosed DSAP population in the U.S. and highlight the substantial burden of a chronic, progressive disease for which no FDA-approved therapies currently exist.

Palvella’s second product candidate, QTORIN™ pitavastatin, is being developed for the treatment of DSAP, with a Phase 2 trial anticipated to commence in the fourth quarter of 2026.

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. 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 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 with respect to the timing of, and anticipated FDA review process for, the NDA for QTORIN™ rapamycin, Palvella’s plans to pursue Breakthrough Therapy Designation, Palvella’s plans to meet with regulatory authorities, Palvella’s expectations regarding the benefits of orphan drug designation and potential benefit of orphan drug exclusivity for QTORIN™ rapamycin for the treatment of microcystic lymphatic malformations, 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 make regulatory submissions on anticipated timelines; 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; Palvella’s limited experience in commercial manufacturing; 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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