U.S. Food and Drug Administration Awards Additional Funding for QTORIN™ Rapamycin for the Treatment of Microcystic Lymphatic Malformations

September 28, 2026

NDA submission completed following positive Phase 3 SELVA results; potential U.S. commercial launch in the first half of 2027, if approved

QTORIN™ rapamycin has the potential to become the first FDA-approved therapy and establish a new standard of care for an estimated more than 30,000 pediatric and adult patients living with microcystic lymphatic malformations in the U.S.

WAYNE, Pa., Sept. 28, 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 that the Company has received a third year of grant funding from the FDA Office of Orphan Products Development. The funding supports the Phase 3 SELVA trial and ongoing open-label extension study of QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatment of microcystic lymphatic malformations. The award follows FDA review of Palvella's annual performance progress report, which included results from the Phase 3 SELVA trial.

"We are grateful for the FDA's continued support of the QTORIN™ rapamycin program, including funding through the Orphan Products Grants Program, Breakthrough Therapy, Fast Track, and Orphan Drug designations, and the opportunity to submit our NDA on a rolling basis," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "Following positive Phase 3 SELVA results and completion of our NDA submission, we are advancing commercial readiness for a potential U.S. launch in the first half of 2027, if approved. We believe QTORIN™ rapamycin has the potential to become the first FDA-approved therapy for microcystic LMs and establish a new standard of care for pediatric and adult patients living with this serious, lifelong disease."

In February 2026, Palvella announced positive topline results from the Phase 3 SELVA trial, which met its primary endpoint, pre-specified key secondary endpoint, and all four secondary efficacy endpoints, with all six efficacy endpoints achieving statistical significance (all $p<0.001$). In August 2026, Palvella completed the submission of its New Drug Application (NDA) for QTORIN™ rapamycin for the treatment of microcystic LMs.

Palvella's Phase 3 SELVA trial was one of only seven new clinical trials selected for funding from 51 applications received by the FDA Orphan Products Grants Program in fiscal year 2024 and the only Phase 3 trial awarded a grant that year. Grant applications are independently reviewed and scored for scientific and technical merit by rare disease and regulatory experts and may involve consultation with the relevant FDA review division. Since its inception, the program has funded clinical trials that have facilitated the approval of more than 85 medical products for rare diseases.

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 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 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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