# Palvella Therapeutics Strengthens QTORIN™ Pitavastatin Intellectual Property with Yale-Licensed U.S. Patent Providing Protection into 2043

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*Yale-licensed U.S. patent provides broad protection for topical mevalonate pathway inhibition in porokeratosis, including disseminated superficial actinic porokeratosis (DSAP)*

*DSAP is a serious, rare, premalignant genetic skin disease affecting an estimated more than 50,000 diagnosed patients in the U.S., with no FDA-approved therapies*

*Palvella plans to initiate a Phase 2 clinical trial of QTORIN™ pitavastatin in DSAP in the second half of 2026*

WAYNE, Pa., May 27, 2026 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc. (Palvella or the "Company") (Nasdaq: PVLA), 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 issuance of U.S. Patent No. 12,636,273 by the United States Patent and Trademark Office. The issued patent, exclusively licensed by Palvella from Yale University, supports the Company's QTORIN™ pitavastatin program for porokeratosis, including disseminated superficial actinic porokeratosis (DSAP).

"This issued patent strengthens the IP position supporting QTORIN™ pitavastatin and represents an important step in advancing our pathogenesis-directed approach to porokeratosis," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella Therapeutics. "QTORIN™ pitavastatin is designed to combine a potent, next-generation statin with Palvella's QTORIN™ platform to enable pathogenesis-directed inhibition of the mevalonate pathway on-target and directly within DSAP-affected tissue. We believe QTORIN™ pitavastatin has the potential to become a first-in-disease therapy for DSAP, a serious, rare, premalignant genetic skin disease affecting an estimated more than 50,000 diagnosed patients in the U.S., with no FDA-approved therapies."

The issued patent, exclusively licensed from Yale University, strengthens Palvella's intellectual property position supporting QTORIN™ pitavastatin for porokeratosis, including DSAP. Building on pioneering work by Keith Choate, M.D., Ph.D., Chair and Professor of Dermatology, Pathology, and Genetics at Yale School of Medicine, the issued claims cover topical administration of HMG-CoA reductase inhibitors, including pitavastatin, for the treatment of porokeratosis, providing protection into 2043 for this pathogenesis-directed treatment approach. In addition to the newly issued Yale IP, Palvella has filed an additional pending application covering the novel QTORIN-derived formulation of pitavastatin and other statins and methods of use.

QTORIN™ pitavastatin is an investigational topical therapy designed to enable pathogenesis-directed inhibition of the mevalonate pathway on-target and directly within affected skin tissue in porokeratosis. Developed with Palvella's proprietary QTORIN™ platform for generating novel topical therapies for serious, rare skin diseases and vascular malformations, QTORIN™ pitavastatin combines a potent, next-generation statin with Palvella's targeted topical approach. Palvella plans to initiate a Phase 2 clinical trial in DSAP in the second half 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 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 and vascular malformations, 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, 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 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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