Palvella Therapeutics Announces Issuance of European Patent Covering Anhydrous Compositions of Rapamycin

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Patent strengthens global intellectual property protection for QTORIN™ rapamycin, Palvella's lead product candidate from the QTORIN™ platform, in development for serious, rare skin diseases and vascular malformations with no FDA-approved therapies

Patent protection extends into 2038

QTORIN™ rapamycin has previously been granted European Orphan Drug Designation for the treatment of microcystic lymphatic malformations, potentially providing 10 years of market exclusivity in the European Union upon approval

There are currently no approved therapies in the European Union for microcystic lymphatic malformations

WAYNE, Pa., March 16, 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 that the European Patent Office (EPO) has issued European Patent No. 3565520, which includes claims covering QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin), the Company's lead product candidate from the QTORIN™ platform. The patent provides protection for anhydrous topical compositions and methods of use for QTORIN™ rapamycin, including for the treatment of microcystic lymphatic malformations, venous malformations, and other diseases associated with dysregulation of the mammalian target of rapamycin (mTOR) pathway.

"Issuance of this European patent represents an important milestone in expanding our global intellectual property protection for QTORIN™ rapamycin," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella Therapeutics. "Palvella's exclusivity strategy combines patent protection, multiple layers of innovative formulation know-how and manufacturing trade secrets, and regulatory exclusivities designed to support durable protection for our therapies. This European patent complements our existing issued patents in the United States, Japan, Australia, and other territories covering anhydrous formulations of rapamycin and associated therapeutic uses. In addition, QTORIN™ rapamycin has already been granted Orphan Drug Designation for the treatment of microcystic lymphatic malformations which, if approved, may provide 10 years of market exclusivity in the European Union."

The patented compositions relate to Palvella's proprietary QTORIN™ anhydrous gel formulation which is designed to locally inhibit the mTOR pathway within affected pathogenic skin tissue, including the dermis, across multiple mTOR-driven diseases while minimizing systemic exposure. The patent, titled "Anhydrous Compositions of mTOR Inhibitors and Methods of Use," includes composition-of-matter and method-of-use claims covering QTORIN™ rapamycin formulated in anhydrous topical compositions. The claims also cover treatment of a range of diseases, including microcystic lymphatic malformations, venous malformations, and other diseases associated with dysregulation of the mammalian target of rapamycin (mTOR) pathway.

Palvella is currently advancing QTORIN™ rapamycin across multiple serious, rare skin diseases and vascular malformations for which there are no U.S. Food and Drug Administration (FDA)-approved therapies, including microcystic lymphatic malformations, cutaneous venous malformations, clinically significant angiokeratomas, and a fourth target clinical indication which the Company anticipates announcing in the second half of 2026.

QTORIN™ rapamycin has previously been granted Orphan Drug Designation from the European Medicines Agency for the treatment of microcystic lymphatic malformations.

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 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, 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 topical 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 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; 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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