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Palvella Therapeutics Announces First Patient Dosed in SELVA Phase 3 Clinical Trial of QTORIN™ 3.9% Rapamycin Anhydrous Gel (QTORIN™ rapamycin) for the Treatment of Microcystic Lymphatic Malformations

Phase 3 single-arm, baseline-controlled trial evaluating QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatment of microcystic lymphatic malformations (microcystic LMs) currently enrolling participants at leading vascular anomaly centers across the U.S.

Microcystic LMs is a chronically debilitating and lifelong genetic disease affecting an estimated more than 30,000 diagnosed patients in the U.S.

QTORIN™ rapamycin has the potential to be the first approved therapy and standard of care in the U.S. for microcystic LMs

WAYNE, PA., November 7, 2024 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc. (Palvella), a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases for which there are no FDA-approved therapies, today announced the first patient has been dosed in SELVA, a multicenter, Phase 3 clinical trial designed to evaluate the safety and efficacy of QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) for the treatment of microcystic lymphatic malformations (microcystic LMs).

"Microcystic LMs result from genetic changes that lead to hyperactivation of the causative PI3K/mTOR pathway resulting in malformed lymphatic networks that protrude through the skin. This results in persistent external lymph fluid drainage, as well as secondary infections and cellulitis that may require urgent medical attention and hospitalization," said Joyce M. Teng, M.D., Ph.D., Professor of Dermatology and Pediatrics at Stanford University School of Medicine and SELVA Principal Investigator. "Because this serious disease is present at birth and progresses over time without regression, it can result in significant morbidity beginning in childhood and have a lifelong impact."

SELVA is a Phase 3, single-arm, baseline-controlled clinical trial of QTORIN™ rapamycin administered topically once daily for the treatment of microcystic LMs. The primary efficacy endpoint in SELVA is the change from baseline in the overall microcystic LM Investigator Global Assessment (mLM-IGA) at week 24. The Phase 3 study is expected to enroll approximately 40 participants, ages six and older, at leading vascular anomaly centers across the U.S. The FDA has granted Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation to QTORIN™ rapamycin for the treatment of microcystic LMs. Additionally, Palvella was awarded up to $2.6 million from the FDA's Office of Orphan Products Development to support the SELVA study.

"We are pleased to have dosed the first patient in our Phase 3 SELVA trial, an important milestone towards our objective of advancing QTORIN™ rapamycin to potential regulatory approvals and U.S. commercialization," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "QTORIN™ rapamycin has the potential to be the first approved therapy and standard of care in the U.S. for the estimated more than 30,000 diagnosed patients suffering from microcystic LMs in the U.S."

QTORIN rapamycin is the lead product candidate from Palvella's QTORIN platform. QTORIN rapamycin is a novel, patented 3.9% rapamycin anhydrous gel which aims to harness the potential therapeutic benefits of rapamycin, a mammalian target of rapamycin (mTOR) inhibitor, while minimizing systemic exposure of rapamycin and potential adverse reactions associated with systemic therapy. QTORIN rapamycin is currently under development for the treatment of microcystic LMs, cutaneous venous malformations, and other serious, functionally debilitating skin diseases driven by the overactivation of the mTOR pathway.

About Microcystic Lymphatic Malformations

Microcystic LMs is a rare, chronically debilitating genetic disease caused by dysregulation of the phosphatidylinositol 3-kinase (PI3K)/mTOR pathway. The disease is characterized by malformed lymphatic vessels that protrude through the skin and persistently leak lymph fluid (lymphorrhea) and bleed, often leading to recurrent serious infections and cellulitis that can cause hospitalization. The natural history of microcystic LMs are persistent and progressive without spontaneous resolution, with symptoms generally worsening during life, including increases in the number and size of malformed vessels that lead to complications and lifetime morbidity. There are currently no FDA-approved treatments for the estimated more than 30,000 diagnosed patients with microcystic LMs in the United States.

About Palvella Therapeutics

Founded and led by rare drug disease drug development veterans, Palvella Therapeutics is a clinical-stage biopharmaceutical company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases 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 genetic skin diseases, many of which are lifelong in nature. Palvella's lead product candidate, QTORIN 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin), is currently in clinical development for microcystic lymphatic malformations (microcystic LMs) and cutaneous venous malformations.

In July 2024, Palvella and Pieris Pharmaceuticals, Inc. (Nasdaq: PIRS) announced they have entered into a definitive merger agreement to combine the companies in an all-stock transaction.

Forward-Looking Statements

This press release contains forward-looking statements concerning the development and commercialization of Palvella's products, the potential benefits and attributes of such products, and Palvella's expectations regarding its prospects, including the potential merger with Pieris Pharmaceuticals. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements. These statements are made as of the date of this press release. Actual results may vary. Palvella undertakes no obligation to update any forward-looking statements for any reason.

No Offer or Solicitation

This press release is not intended to and does not constitute an offer to sell or the solicitation of an offer to subscribe for or buy or an invitation to purchase or subscribe for any securities or the solicitation of any vote in any jurisdiction pursuant to the proposed transaction or otherwise, nor shall there be any sale, issuance or transfer of securities in any jurisdiction in contravention of applicable law. No offer of securities shall be made except by means of a prospectus meeting the requirements of the Securities Act. Subject to certain exceptions to be approved by the relevant regulators or certain facts to be ascertained, the public offer will not be made directly or indirectly, in or into any jurisdiction where to do so would constitute a violation of the laws of such jurisdiction, or by use of the mails or by any means or instrumentality (including without limitation, telephone and the internet) of interstate or foreign commerce, or any facility of a national securities exchange, of any such jurisdiction.

NEITHER THE SEC NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THE SECURITIES OR DETERMINED IF THIS PRESS RELEASE IS TRUTHFUL OR COMPLETE.

Important Additional Information About the Proposed Transactions Will be Filed with the SEC

In connection with the proposed transaction between Pieris and Palvella, Pieris intends to file relevant materials with the SEC, including a registration statement on Form S-4 that will contain a proxy statement and prospectus of Pieris and an information statement of Palvella. PIERIS URGES INVESTORS AND STOCKHOLDERS TO READ THESE MATERIALS CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THESE MATERIALS, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT PIERIS, PALVELLA, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and stockholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Pieris with the SEC (when they become available) through the website maintained by the SEC at www.sec.gov. In addition, investors and stockholders will be able to obtain free copies of the proxy statement/prospectus/information statement and other documents filed by Pieris with the SEC free of charge on Pieris' website at www.pieris.com, or by contacting Investor Relations by email at info@pieris.com. Investors and stockholders are urged to read the proxy statement/prospectus/information statement and the other relevant materials when they become available before making any voting or investment decision with respect to the proposed transaction.

Participants in the Solicitation

Palvella, Pieris and their respective directors and executive officers may be considered participants in the solicitation of proxies in connection with the proposed transaction. Information about Pieris' directors and executive officers is included in Pieris' most recent Annual Report on Form 10-K, as amended, including any information incorporated therein by reference, as filed with the SEC on March 29, 2024, and amended on April 29, 2024. Additional information regarding the persons who may be deemed participants in the solicitation of proxies will be included in the proxy statement/prospectus/information statement relating to the proposed transaction when it is filed with the SEC. These documents can be obtained free of charge from the sources indicated above.

Contact Information

Investors
Wesley H. Kaupinen
Founder and CEO, Palvella Therapeutics
wes.kaupinen@palvellatx.com

Media
Stephanie Jacobson
Managing Director, Argot Partners
palvella@argotpartners.com