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Palvella Therapeutics Appoints Matthew E. Korenberg as Chief Financial Officer

Mr. Korenberg is a seasoned executive with significant operational and financial leadership experience, including senior roles at Ligand Pharmaceuticals (NASDAQ: LGND) and in healthcare investment banking at The Goldman Sachs Group (NYSE: GS)

WAYNE, Pa., October 17, 2024 (GLOBE NEWSWIRE) — Palvella Therapeutics, Inc., 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 appointment of Matthew E. Korenberg as Chief Financial Officer, effective immediately. Mr. Korenberg is a seasoned operational and financial leader with more than 27 years of experience in senior executive roles in biotech companies and healthcare investment banking. Throughout his career, he has served as an operator of, and advisor to, biotechnology and pharmaceutical companies with a primary focus on fundraising, partnering and licensing deals, acquisitions, as well as overseeing public company operations related to investor relations and public reporting.

"I am thrilled to welcome Matt to Palvella and to our senior leadership team," said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. "Matt's proven track record in corporate finance, capital markets, and public company corporate strategy and operations will be instrumental to advancing our rare disease pipeline, including accelerating our lead product candidate QTORIN™ rapamycin to potential regulatory approvals and U.S. commercialization. We look forward to Matt's significant contributions towards achieving our vision of becoming the leading rare disease company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases."

Mr. Korenberg joins Palvella from Ligand Pharmaceuticals Inc. (NASDAQ: LGND), where he served as President and Chief Operating Officer since 2022 and Chief Financial Officer from 2015 to 2022. Prior to Ligand Pharmaceuticals, Mr. Korenberg was the founder, Chief Executive Officer, and a director of NeuroCircuit Therapeutics, a company focused on developing drugs to treat genetic disorders of the brain with an initial focus on Down syndrome. Earlier in his career, Mr. Korenberg served as a Managing Director and member of the healthcare investment banking team at The Goldman Sachs Group from 1999 to 2013. During his 14-year tenure at Goldman Sachs, Mr. Korenberg focused on advising and financing companies in the biotechnology and pharmaceutical sectors. Mr. Korenberg currently serves on the board of directors, including the audit committee, of Lifecore Biomedical Inc. (NASDAQ: LFCR), a fully integrated contract development and manufacturing organization. He earned a B.B.A. in Finance and Accounting from the University of Michigan.

"I am excited to join Palvella at such a dynamic time. The combination of a dedicated, seasoned leadership team, patented QTORIN™ platform technology, and promising late-stage rare disease pipeline make the company well-positioned for growth," said Mr. Korenberg. "I look forward to actively contributing to Palvella's transformation to becoming a public entity and one that is the leading rare disease company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases."

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 QTORIN™ Platform and QTORIN™ rapamycin
Palvella's research team developed QTORIN, a patented and versatile platform designed to generate novel topical therapies that penetrate the deep layers of the skin to locally treat a broad spectrum of serious, rare genetic skin diseases. Well-accepted mechanisms of action of rapamycin and other therapeutic agents represent potential therapies for rare genetic skin diseases. However, the adverse event profile of those agents through systemic exposure poses significant barriers to patient adoption. Palvella's QTORIN product candidates are designed for targeted, localized delivery of therapeutic agents to pathogenic tissue of interest while minimizing systemic absorption and thereby reducing the risk of unwanted adverse events associated with systemic therapy.

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. QTORIN rapamycin has received FDA Breakthrough Therapy Designation, Fast Track Designation, and Orphan Drug Designation for microcystic LMs, and Fast Track Designation for venous malformations. QTORIN rapamycin is protected by multiple issued composition patents in the U.S. and Japan and has several pending patent applications covering anhydrous gel formulations of rapamycin in the U.S., Europe, and Japan.

In the third quarter of 2024, Palvella initiated SELVA, a 24-week, Phase 3, single-arm, baseline-controlled clinical trial of QTORIN rapamycin for the treatment of microcystic LMs. The study's primary and key secondary endpoints are clinician-reported outcomes. The study is expected to enroll 40 subjects at leading vascular anomaly centers across the U.S.

QTORIN rapamycin is for investigational use only and has not been approved or cleared by the FDA or by any other regulatory agency.

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 the company'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.

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