Palvella Therapeutics Announces Series D Financing of Up to $37.7 Million to Accelerate Late-Stage Development and Support Commercialization of Novel Therapies for Serious, Rare Genetic Skin Diseases

January 05, 2023 16:30 ET | Source: **Palvella Therapeutics**

Led by new investor Petrichor, with participation from new and existing investors

Lead product candidate, QTORIN™ rapamycin, in late-stage clinical development for serious, rare genetic skin diseases with no FDA-approved therapies

Top-line data expected in mid-2023 from Phase 3 pivotal study evaluating QTORIN™ rapamycin in Pachyonychia Congenita

WAYNE, Pa., Jan. 05, 2023 (GLOBE NEWSWIRE) -- Palvella Therapeutics, Inc., a late clinical-stage biopharmaceutical company whose vision is to become the leading rare disease company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases in indications for which there are no FDA-approved therapies, today announced the initial closing of its Series D financing of up to $37.7 million. The financing was led by Petrichor and included new investor Gore Range Capital. Existing investors Samsara BioCapital, BVF Partners L.P., Agent Capital, Nolan Capital, and BioAdvance also participated in the financing. Tadd Wessel, Founder and Managing Partner of Petrichor, has joined the Palvella Board of Directors.

Proceeds from the financing will be used to advance the development of Palvella's lead product candidate QTORIN™ 3.9% rapamycin anhydrous gel

(QTORIN™ rapamycin) for the treatment of Pachyonychia Congenita (PC), treatment of Microcystic Lymphatic Malformations (Microcystic LM), and for the prevention of Basal Cell Carcinomas (BCCs) in Gorlin Syndrome (GS). These three initial clinical indications for QTORIN™ rapamycin share similarities in the underlying disease pathology whereby the mammalian target of rapamycin, or mTOR, pathway is overactivated leading to chronically debilitating disease burdens for affected individuals. By inhibiting the mTOR pathway and limiting the systemic exposure of rapamycin, we believe QTORIN™ rapamycin has the potential to become the first approved therapy and standard of care for these indications. QTORIN™ rapamycin has received FDA Fast Track Designation for PC, Microcystic LM, and for the prevention of BCCs in GS.

“We greatly appreciate the support of our investors, new and existing, and their conviction in our ability to develop and commercialize novel therapies for serious, rare genetic skin diseases,” said Wes Kaupinen, Founder and Chief Executive Officer of Palvella. “The funding will accelerate our efforts to develop and commercialize QTORIN™ rapamycin for individuals suffering from Pachyonychia Congenita, Microcystic Lymphatic Malformations, and Gorlin Syndrome.”

Palvella anticipates several key catalysts within the next three fiscal quarters, including reporting Phase 2 top-line results in Microcystic LM in the first quarter of 2023, Phase 2b top-line results in GS in the first half of 2023, and Phase 3 top-line results in PC in mid-2023.

“Palvella has advanced clinical development of its product candidates in multiple underserved indications with high unmet medical need, generating compelling clinical evidence that supports the ongoing and planned Phase 3 studies,” said Mr. Wessel. “We are pleased to partner with the Palvella team to help them realize their vision of becoming the leading rare disease company focused on novel therapies for serious, rare genetic skin diseases.”

Cowen served as exclusive placement agent on the financing. Troutman Pepper Hamilton Sanders LLP served as legal counsel to Palvella.

About Palvella Therapeutics

Founded and led by rare disease veterans, Palvella Therapeutics is a late clinical-stage biopharmaceutical company whose vision is to become the leading rare disease company focused on developing and commercializing novel therapies to treat patients suffering from serious, rare genetic skin diseases in indications for which there are no FDA-approved therapies. Palvella’s development model involves partnering with patient advocacy

organizations and their patient registries to design accelerated development programs aimed at expediting the introduction of targeted therapies to patients who currently lack any approved treatment options. We are developing a broad pipeline of product candidates based on our patented QTORIN™ platform, with an initial focus on serious, rare genetic skin diseases, many of which are lifelong in nature. Our lead product candidate, QTORIN™ 3.9% rapamycin anhydrous gel (QTORIN™ rapamycin) is currently in late-stage clinical development for Pachyonychia Congenita (PC), Microcystic Lymphatic Malformations (Microcystic LM), and the prevention of Basal Cell Carcinomas (BCCs) in Gorlin Syndrome (GS). QTORIN™ rapamycin has received FDA Fast Track Designation for PC, Microcystic LM, and for the prevention of BCCs in GS.

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

About Petrichor

Petrichor partners with world-class healthcare managers and businesses to provide customized investment structures and support. The Petrichor team has completed over 125 investments representing more than $6 billion in invested capital and has held over 50 board seats. Petrichor maintains a deep in-house understanding of healthcare products and services, including scientific, technical, and commercial expertise. This healthcare expertise, together with a breadth of experience investing across sectors, geographies, and capital structures, provides a unique combination to help build successful companies.

For more information on Petrichor, please see www.petrichorcap.com or contact the firm at info@petrichorcap.com.

About Gore Range Capital

Gore Range Capital is the only venture capital firm focused exclusively on innovation in the skin health and aging space. Since 2015, it has partnered with industry pioneers and portfolio companies to find new treatments for dermatological conditions and bring skin health innovations to market. For more information, visit: https://www.gorerangecapital.com.

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. 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.

Contact Information

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

Media:
Marcy Nanus
Managing Partner, Trilon Advisors, LLC
mnanus@trilonadvisors.com