Palvella Therapeutics Announces Late-Breaking Oral Presentation at the 15th World Congress of Pediatric Dermatology

April 2, 2025

Presentation to highlight SELVA, a 24-week, Phase 3, single-arm, baseline-controlled clinical trial of QTORIN™ rapamycin 3.9% anhydrous gel for the treatment of microcystic lymphatic malformations

WAYNE, Pa., April 02, 2025 (GLOBE NEWSWIRE) -- (Nasdaq: PVLA) Palvella Therapeutics, Inc. (Palvella or "the Company"), 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 U.S. Food and Drug Administration (FDA)-approved therapies, today announced a late-breaking oral presentation at the upcoming 15th World Congress of Pediatric Dermatology, taking place April 8-11, 2025, in Buenos Aires, Argentina.

The oral presentation will highlight SELVA, a 24-week, Phase 3, single-arm, baseline-controlled clinical trial of QTORIN™ rapamycin 3.9% anhydrous gel for the treatment of microcystic lymphatic malformations. The details are as follows:

15th World Congress of Pediatric Dermatology Abstract
Title: SELVA: A Phase 3 study with a fit-for-purpose primary endpoint evaluating QTORIN™ 3.9% rapamycin anhydrous gel in the treatment of microcystic lymphatic malformations in patients 3 years of age and older
Presenter: Amy Paller, M.S., M.D., Walter J. Hamlin Professor and Chair of Dermatology, Professor of Pediatrics, and Principal Investigator of the NIH-funded Skin Biology and Diseases Resource-based Center at Northwestern University's Feinberg School of Medicine
Session: Free Communications VII: Case Series & Clinical or Epidemiological Studies
Session Date, Time & Location: Friday, April 11, 2025 between 8:30-10:00 am GMT-3 in room F

About Microcystic Lymphatic Malformations

Microcystic LMs are a rare, chronically debilitating genetic disease caused by dysregulation of the phosphatidylinositol 3-kinase (PI3K)/mammalian target of rapamycin (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 is 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 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 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 being evaluated in the Phase 3 SELVA clinical trial in microcystic lymphatic malformations and the Phase 2 TOIVA clinical trial in cutaneous venous malformations. For more information, please visit www.palvellatx.com or follow Palvella on LinkedIn or X (formerly known as Twitter).

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

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