Verrica Pharmaceuticals Announces that Development Partner Torii Pharmaceutical Files New Drug Application of TO-208 the Treatment of Molluscum Contagiosum in Japan

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WEST CHESTER, Pa., Dec. 06, 2024 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (“Verrica” or the “Company”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced its development and commercialization partner, Torii Pharmaceutical Co. Ltd. (“Torii”), submitted a New Drug Application (“NDA”) of TO-208 (referred to as VP-102 and marketed as YCANTH® in the U.S.) for the treatment of Molluscum Contagiosum (“molluscum”) in Japan.

“Torii continues to be an outstanding partner in advancing TO-208 for the treatment of molluscum, and today’s NDA submission represents the next critical milestone towards bringing to market the first therapeutic for addressing this indication in Japan,” said Jayson Rieger, Ph.D., MBA, President and Chief Executive Officer of Verrica. “With an estimated prevalence of approximately 1.6 million cases, molluscum represents a large and underserved patient population in Japan, and we believe Torii’s therapeutic expertise and commercial infrastructure in dermatology will maximize the opportunity to address this significant unmet need.”

TO-208 is a skin disease treatment drug candidate containing cantharidin as an active ingredient. In the Phase 3 clinical study of TO-208 in patients with molluscum contagiosum (≥2 years old) in Japan, the primary endpoint of efficacy has met superiority to the vehicle. Furthermore, the safety profile of TO-208 in the study was consistent to prior studies in the United States and there were no observed issues of tolerability for the application.

Torii and Verrica executed an exclusive license agreement for the development and commercialization of TO-208 for the treatment of molluscum and common warts in Japan in March 2021.

Verrica received manufacturing and marketing approval of VP-102 to treat molluscum contagiosum in the U.S. in July 2023. Verrica has marketed VP-102 under the brand name YCANTH® in the U.S. since August 2023 and has completed a Phase 2 clinical study of VP-102 for the treatment of common warts and a Phase 2 clinical study of VP-102 for the treatment of external genital warts in the U.S.

About YCANTH® (VP-102)
YCANTH® is a proprietary drug-device combination product that contains a GMP-controlled formulation of cantharidin delivered via a single-use applicator that allows for precise topical dosing and targeted administration for the treatment of molluscum. YCANTH® is the first and only commercially available product approved by the FDA to treat adult and pediatric patients two years of age and older with molluscum contagiosum — a common, highly contagious skin disease that affects an estimated six million people in the United States, primarily children. Approval of YCANTH® was based upon the positive results from two Phase 3 clinical trials in approximately 500 patients which demonstrated that YCANTH® was a safe and effective therapeutic for the treatment of molluscum. Approximately 228 million lives are eligible to receive YCANTH® covered by insurance. YCANTH® is available to all patients with and without insurance coverage for $25 per treatment, and further financial assistance is available for patients in need. Please visit YCANTHPro.com for additional information.

YCANTH® should only be administered by a trained healthcare professional. YCANTH® is not for home use.

About Verrica Pharmaceuticals Inc.
Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica’s product YCANTH® (VP-102) (cantharidin), is the first and only commercially available treatment approved by the FDA to treat adult and pediatric patients two years of age and older with molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6 million people in the United States, primarily children. YCANTH® (VP-102) is also in development to treat common warts and external genital warts, two of the largest remaining unmet needs in medical dermatology. Verrica is developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. Verrica has also entered a worldwide license agreement with Lytix Biopharma AS to develop and commercialize VP-315 (formerly LTX-315 and VP-LTX-315) for non-melanoma skin cancers including basal cell carcinoma and squamous cell carcinoma.

Forward-Looking Statements
Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Verrica’s current beliefs and expectations. These forward-looking statements include statements about Verrica’s expectations with regard to the clinical development and potential commercialization of TO-208 for the treatment of molluscum in Japan, Torri’s ability to maximize the opportunity in Japan, the clinical development of YCANTH (VP-102) for additional indications, and the benefits of Verrica’s product candidates, including YCANTH (VP-102). These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include

risks and uncertainties related to market conditions, satisfaction of customary closing conditions related to the proposed public offering and other risks and uncertainties that are described in Verrica's Annual Report on Form 10-K for the year ended December 31, 2023, Verrica's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 and other filings Verrica makes with the SEC. Any forward-looking statements speak only as of the date of this press release and are based on information available to Verrica as of the date of this release, and Verrica assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Source: Verrica Pharmaceuticals Inc.