



Verrica Pharmaceuticals Announces Resubmission of New Drug Application for VP-102 for the Treatment of Molluscum Contagiosum

December 23, 2020

WEST CHESTER, Pa., Dec. 23, 2020 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. ("Verrica") (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that it has resubmitted the New Drug Application (NDA) for VP-102 for the treatment of molluscum contagiosum (molluscum) to the U.S. Food and Drug Administration (FDA). The NDA for VP-102 was resubmitted based on the outcome and final minutes of a Type A meeting with the FDA, which was conducted to obtain clarity on the Complete Response Letter (CRL) issued by the FDA in July 2020.

"We are pleased that we were able to expeditiously provide a comprehensive resubmission of the NDA focused on the Chemistry, Manufacturing and Controls (CMC) information as well as Human Factors validation identified by the FDA in its Complete Response Letter," said Ted White, President and Chief Executive Officer, Verrica. "We look forward to working with the FDA through the review process, and if approved, bringing VP-102 to patients as the first FDA-approved treatment option for molluscum."

About VP-102

Verrica's lead product candidate, VP-102, is a proprietary drug-device combination that contains a GMP-controlled formulation of cantharidin (0.7% w/v) delivered via a single-use applicator that allows for precise topical dosing and targeted administration. VP-102 is currently under U.S. Food and Drug Administration (FDA) review and could potentially be the first product approved by the FDA to treat molluscum contagiosum — a common, highly contagious skin disease that affects an estimated six million people in the United States, primarily children. If approved, VP-102 will be marketed in the United States under the conditionally accepted brand name YCANTH™. In addition, Verrica has successfully completed a Phase 2 study of VP-102 for the treatment of common warts and a Phase 2 study of VP-102 for the treatment of external genital warts.

About Molluscum Contagiosum (Molluscum)

There are currently no FDA-approved treatments for molluscum, a highly contagious viral skin disease that affects approximately six million people — primarily children — in the United States. Molluscum is caused by a pox virus that produces distinctive raised, skin-toned-to-pink-colored lesions that can cause pain, inflammation, itching and bacterial infection. It is easily transmitted through direct skin-to-skin contact or through fomites (objects that carry the disease like toys, towels or wet surfaces) and can spread to other parts of the body or to other people, including siblings. The lesions can be found on most areas of the body and may carry substantial social stigma. Without treatment, molluscum can last for an average of 13 months, and in some cases, up to several years.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica's late-stage product candidate, VP-102, is in development to treat molluscum contagiosum (molluscum), common warts and external genital warts, three of the largest unmet needs in medical dermatology. Verrica is also developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. The Company has also entered a worldwide license agreement with Lytx Biopharma AS to develop and commercialize LTX-315 for dermatologic oncology conditions. For more information, visit www.verrica.com.

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 expectations regarding the Company's expectations with regard to its interactions and communications with the FDA, the potential approval of the NDA for VP-102 following resubmission and the potential benefits and potential commercialization of VP-102 for the treatment of molluscum, if approved. 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 uncertainties inherent in the drug development process and the regulatory approval process, Verrica's reliance on third parties over which it may not always have full control, uncertainties related to the COVID-19 pandemic and other risks and uncertainties that are described in Verrica's Annual Report on Form 10-K for the year ended December 31, 2019, Verrica's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, and other filings Verrica makes with the U.S. Securities and Exchange Commission. 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.