



## **Verrica Pharmaceuticals Receives Complete Response Letter from the FDA identifying deficiencies at a facility of a Contract Manufacturer for its New Drug Application for VP-102 for the Treatment of Molluscum Contagiosum**

September 20, 2021

*No Specific Deficiencies Related to the Manufacturing of VP-102 Identified by FDA in its General Inspection of a Facility of the Contract Manufacturer*

*No Clinical, Safety or CMC Issues Specific to VP-102 Identified*

WEST CHESTER, Pa., Sept. 20, 2021 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (the "Company") (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding its New Drug Application (NDA) for VP-102 for the treatment of molluscum contagiosum (molluscum). The Company had previously disclosed that the FDA extended the Prescription Drug User Fee Act (PDUFA) goal date for the NDA by three months to September 23, 2021 to allow the Agency additional time to review information submitted by the Company in response to comments from the Agency regarding the Company's human factors study.

According to the CRL, the FDA has identified deficiencies at a facility of a contract manufacturing organization (CMO), which are not specifically related to the manufacturing of VP-102 but instead raise general quality issues at the facility. At no time prior to the CRL was the Company notified by the FDA of any deficiencies at the CMO related specifically to the manufacturing of VP-102 or that their general investigation of the facility would have any impact on the Company's NDA. More importantly, the FDA did not identify any clinical, safety or product specific Chemistry, Manufacturing, and Controls (CMC) deficiencies related to VP-102.

The Company understands from the CMO that it has implemented corrective actions to address the Agency's concerns and the CMO has advised Verrica that it is expecting a satisfactory resolution of the facility's identified deficiencies from the FDA within the next 30 business days. During this timeframe, the Company will engage with the Agency to demonstrate that the Company's good manufacturing practices, controls and processes ensure that any deficiencies at the CMO do not impact the efficacy, safety or quality of VP-102.

"We remain confident that we have a path forward for VP-102 as a potential treatment option for molluscum, a highly contagious viral skin disease affecting approximately six million people in the United States - primarily children - for which there are currently no FDA-approved treatments," said Ted White, Verrica's President and Chief Executive Officer.

### **About Molluscum Contagiosum (Molluscum)**

Molluscum is 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 VP-102**

Verrica's lead product candidate, VP-102, is a proprietary drug-device combination product 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. A Complete Response Letter was received from the FDA regarding the NDA for VP-102 on September 17, 2021. 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 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, 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 Lytix Biopharma AS to develop and commercialize LTX-315 for dermatologic oncology conditions. For more information, visit [www.verrica.com](http://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 interactions with the FDA, including the FDA’s potential favorable response, and the timing of such response to the CMO’s corrective actions, the potential approval of the NDA for VP-102, 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, 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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