

Reinventing Skin Science

Verrica Pharmaceuticals Announces Acceptance by FDA of NDA Resubmission for VP-102 for the Treatment of Molluscum Contagiosum

December 15, 2021

WEST CHESTER, Pa., Dec. 15, 2021 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. ("Verrica") (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) acknowledged that Verrica's resubmitted New Drug Application (NDA) for VP-102 for the treatment of molluscum contagiosum (molluscum) was complete and assigned a Prescription Drug User Fee Act (PDUFA) goal date of May 24, 2022.

"We are pleased that the FDA has accepted our NDA resubmission for VP-102," said Ted White, Verrica's President and Chief Executive Officer. "While we recognize the demands of the Agency's current workload, we intend to work with the FDA toward approval as quickly as possible based on the limited changes in our resubmission. We continue to be encouraged by the overwhelming demand from both caregivers and the medical community for an FDA-approved treatment for molluscum, one of the largest unmet needs in medical dermatology."

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. If approved, VP-102 would 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. VP-102 would be marketed in the United States under the conditionally accepted brand name YCANTHTM. 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 — irthe 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, 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.

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 potential timing and approval of the NDA for VP-102 [and interactions with the FDA]. 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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