



Verrica Pharmaceuticals Announces FDA Filing Acceptance of New Drug Application for VP-102 for the Treatment of Molluscum Contagiosum

November 27, 2019

- PDUFA date assigned is July 13, 2020 -

- VP-102 (cantharidin 0.7% Topical Solution) could potentially be the first FDA-approved treatment for molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6 million people in the United States, primarily children -

WEST CHESTER, Pa., Nov. 27, 2019 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. ("Verrica") (Nasdaq: VRCA), a medical dermatology company, today announced that its New Drug Application (NDA) for VP-102 (cantharidin 0.7% Topical Solution), a proprietary topical therapy for the treatment of molluscum contagiosum (molluscum), has been accepted for filing by the U.S. Food and Drug Administration (FDA). The Prescription Drug User Fee Act (PDUFA) goal date assigned by the FDA for this NDA is July 13, 2020.

"There are no FDA-approved treatments currently available to patients diagnosed with molluscum, the majority of whom are children, leaving caregivers to choose between a wait-and-see approach or treatments with unproven efficacy," said Ted White, President and Chief Executive Officer, Verrica. "Left untreated, molluscum is easily transmitted, with lesions persisting an average of 13 months, and molluscum can last up to several years, as seen in our clinical trials. The acceptance of this NDA for review is the next step toward bringing patients and their caregivers a safe and effective topical therapy for this common, highly contagious viral skin disease that carries a substantial social stigma. We look forward to working closely with the FDA during this review period."

The NDA is based on positive results from two identical Phase 3 randomized, double-blind, multicenter clinical trials (CAMP-1 and CAMP-2) that evaluated the safety and efficacy of VP-102 compared to placebo in patients two years of age and older diagnosed with molluscum. CAMP-1 was conducted under a SPA (Special Protocol Assessment) with the FDA. In both trials, a clinically and statistically significant number of patients treated with VP-102 met the primary endpoint of complete clearance of all treatable molluscum lesions.

VP-102 was well-tolerated in both trials, with no serious adverse events reported in VP-102-treated subjects.

About Verrica Pharmaceuticals Inc.

Verrica is a medical dermatology company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases. The Company's late-stage product candidate, VP-102, is a potential first-in-class topical therapy for the treatment of molluscum contagiosum and common warts. Molluscum is a highly contagious viral skin infection affecting approximately six million people, primarily children, in the United States, and common warts are contagious skin growths affecting 22 million people. There are currently no FDA-approved treatments for molluscum or common warts. Following positive topline results from two pivotal Phase 3 trials, the Company submitted an NDA on September 13, 2019 for VP-102 for the treatment of molluscum; on November 26, 2019, the Company received notice that the FDA accepted the NDA for filing with a PDUFA goal date of July 13, 2020. Verrica intends to commence a Phase 3 trial in the first quarter of 2020 to evaluate VP-102 for common warts. VP-102 is also currently in a Phase 2 trial for the treatment of external genital warts. A second product candidate, VP-103, is in pre-clinical development for plantar warts. For more information, visit www.verrica.com.

Forward-Looking Statement

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 benefits of VP-102 for the treatment of molluscum and the clinical development of VP-102 for additional indications, including common warts, external genital warts and plantar warts. 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, and other risks and uncertainties that are described in Verrica's Annual Report on Form 10-K for the year ended December 31, 2018, filed with the U.S. Securities and Exchange Commission on March 7, 2019, 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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