Verrica Pharmaceuticals Submits New Drug Application to U.S. Food and Drug Administration for VP-102 for the Treatment of Molluscum Contagiosum

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No FDA-approved treatments are currently available for this highly contagious, primarily pediatric, viral skin infection affecting an estimated 6 million people in the United States

WEST CHESTER, Pa., Sept. 16, 2019 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. ("Verrica") (Nasdaq: VRCA), a medical dermatology company committed to the development and commercialization of novel treatments that provide meaningful benefit for people living with skin diseases, today announced that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for VP-102 (cantharidin 0.7% Topical Solution), a proprietary topical therapy, for the treatment of molluscum contagiosum (molluscum). No FDA-approved treatments are currently available for molluscum, a common, highly contagious skin disease affecting an estimated 6 million people in the United States, primarily children. Without treatment, molluscum can persist for an average of 13 months, with some cases remaining unresolved for several years.

"Molluscum is a viral skin infection that is highly contagious, spreads rapidly, and is significantly undertreated, with no FDA-approved therapeutic options," said Ted White, President and Chief Executive Officer, Verrica. "The NDA submission potentially brings us one step closer to our goal of providing patients — particularly children and their caregivers — with a safe and effective therapy for molluscum with our proprietary single-use applicator. If approved, VP-102 has the potential to become the standard of care for this disease."

The 505(b)(1) NDA is supported by the positive results from two double-blind Phase 3 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. The CAMP-1 and CAMP-2 studies enrolled 528 patients in total and were conducted at 31 centers in the United States. Each trial demonstrated superior efficacy of VP-102 compared to placebo with statistically significant differences on the primary endpoint of complete clearance of all treatable molluscum lesions. Specific results from CAMP-1 and CAMP-2 demonstrated 46% and 54%, respectively, of subjects treated with VP-102 achieved complete clearance at day 84, versus 18% and 13% of subjects in the placebo groups ($p<0.0001$). By the end of the trials (Day 84), VP-102 treated subjects had a 69% and 83% mean reduction in molluscum lesions, a pre-specified endpoint, in CAMP-1 and CAMP-2, respectively, compared to a 20% increase and 19% reduction for subjects on placebo. VP-102 was well-tolerated in both trials, with no serious adverse events reported in VP-102 treated subjects.

Verrica has been granted a waiver by the FDA for the NDA application user fee under the small business waiver provision of the Federal Food, Drug and Cosmetic Act.

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 a NDA for VP-102 for the treatment of molluscum. Verrica is planning to meet with the FDA to determine next steps on the development of VP-102 for common warts following positive Phase 2 results. 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. 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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