Verrica Pharmaceuticals Announces Positive Topline Results in Phase 2 Clinical Study of VP-102 in Patients with External Genital Warts (CARE-1)

- 35% of subjects treated with VP-102 achieved complete clearance of all treatable genital warts vs 2.4% for vehicle (p=0.0001) -

- VP-102 was well-tolerated with no reported serious adverse events related to VP-102 -

- Approximately 500,000 to 1 million cases of EGW are newly diagnosed per year in the United States -

- Based on positive outcome, Verrica will request an End-of-Phase 2 meeting with the FDA -

WEST CHESTER, Pa., November 10, 2020 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (Verrica) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced positive topline results from its Phase 2 CARE-1 clinical study of VP-102, a novel topical therapy containing a solution of 0.7% (w/v) cantharidin in a proprietary single-use applicator, in external genital warts (EGW). VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable EGW at Day 84 and the secondary endpoint of the percentage reduction of EGW at Day 84.

“The positive results of the Phase 2 CARE-1 trial suggest that VP-102 has the potential to provide patients and physicians with a well-tolerated and effective option for treatment,” said Gary Goldenberg, MD, Chief Medical Officer of Verrica. “Based on the positive outcome from CARE-1, we intend to request an End-of-Phase 2 meeting with the FDA for the treatment of EGW in the first quarter of 2021.”

”EGW, otherwise known as condyloma acuminata, are one of the most common sexually-transmitted infections in the U.S., often resulting in substantial social stigma, negative impact on quality of life, and an increased risk of HPV-related cervical cancer,” said Neal Bhatia, MD, Director of Clinical Dermatology at Therapeutics Clinical Research in San Diego. “Undertreatment of EGW presents an interdisciplinary public health issue, as patients often seek treatment from a variety of sources including dermatologists, urologists, gynecologists, and primary care physicians. Newer medical therapeutic advances may offer more tolerable and effective approaches to controlling the spread of EGW and therefore can improve outcomes for these patients.”

CARE-1 was a Phase 2, double-blind, vehicle-controlled clinical study of VP-102 to determine the dose regimen, efficacy, safety, and tolerability of VP-102 in subjects with EGW in subjects 18 years of age or older. The study included two sequential parts: Part A and Part B. Part A was conducted in 18 subjects at four research sites. Subjects received treatment with VP-102 to treatable EGW every 21 days for up to four treatments and were told to wash off VP-102 within either 2, 6, or 24 hours of application. Safety results from Part A supported use of VP-102 for both 6-hour and 24-hour treatment exposures in Part B.

Part B was conducted in an additional 87 subjects at nine research sites comparing vehicle to VP-102 applied for either 6 or 24 hours for up to four treatments. The primary analyses were conducted at Day 84. Topline analyses included data from the assessment of EGW at study visits at days 21, 42, 63, and 84.

Study Results and Demographics:

- Subjects presented with a mean wart count of 8.2 with a range of 2 to 30 EGW at baseline. Approximately 50% of subjects had EGW for one year or longer; approximately 23% of subjects had EGW for more than five years.
- Pooled results from the 6- and 24-hour treatment exposures showed 35.1% (20/57) of subjects treated with VP-102 achieved complete clearance of all treatable EGW at Day 84 compared to 2.4% (1/42) of subjects treated with vehicle (p=0.0001).
- For both the 6- and 24-hour treatment exposures, subjects treated with VP-102 achieved statistically significantly larger reductions in percent change from baseline in the number of treatable EGW compared to vehicle at Day 84: 6-hour (p< 0.0001), 24-hour group (p=0.0003).
- VP-102 was well-tolerated. Side effects experienced by the VP-102 treated subjects were consistent with the pharmacodynamic action of cantharidin as a blistering agent. These side effects were primarily mild-to-moderate and included application site vesicles, pain and erythema. No subjects discontinued from the study due to adverse events and there were no serious adverse events reported that were considered related to treatment by the investigator.

In addition to requesting an End-of-Phase 2 meeting with the FDA on next steps for the development of VP-102 for the treatment of EGW, Verrica plans to submit the Phase 2 CARE-1 data for presentation at future medical meetings and for publication in a peer-reviewed medical journal.

About Genital Warts

Genital warts (also known as anogenital warts or condyloma acuminatum) are a sexually transmitted viral infection caused by multiple different types of the human papilloma virus (HPV). Approximately 500,000 to 1 million cases of EGW are newly diagnosed per year in the United States, with clinically apparent warts presenting in 1% of the sexually active population (Yanofsky 2012 *Clinical and Aesthetic Dermatol*). HPV is spread through direct skin-to-skin contact, usually during oral, genital, or anal sexual contact with an infected partner. Diagnosis of genital warts is usually made by visual inspection and can be confirmed by biopsy. The four morphologic types of genital warts are cauliflower-shaped, smooth papular, keratotic, and flat. Genital warts cause few symptoms but can occasionally be painful. Conditions known to predispose women to infection with HPV include local trauma, diabetes, and immuno-suppression.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. The Company's late-stage product candidate, VP-102, is a potential first-in-class drug-device combination product containing a topical therapy for the treatment of molluscum contagiosum. Verrica submitted an NDA for VP-102 for the treatment of molluscum in September 2019. A Complete Response Letter was received from the FDA regarding the NDA for VP-102 on July 13, 2020. In October 2020, Verrica participated in a Type A meeting with the FDA. Verrica expects to resubmit its New Drug Application for VP-102 for the treatment of molluscum in the first quarter of

2021. 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. The Company is also developing VP-103, its third cantharidin-based product candidate, for the treatment of 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 Company's expectations with regard to the potential benefits and clinical development plan for VP-102 for the treatment of EGW, Verrica's interactions and communications with the FDA, and the potential approval of VP-102 to treat EGW, common warts and molluscum. 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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