Verrica Pharmaceuticals Achieves Positive Topline Results in Phase 2 Clinical Study of VP-102 in Patients with Common Warts

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51% of subjects in Cohort 2 achieved complete clearance of all treatable warts

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

Common warts affect approximately 22 million people in the United States

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

Management to host webcast and conference call tomorrow at 8 a.m. ET

WEST CHESTER, Pa., June 26, 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 positive topline results from its COVE-1 Phase 2 open label clinical study of VP-102 for the treatment of verruca vulgaris, or common warts. COVE-1 included two cohorts that evaluated the safety and efficacy of VP-102, a novel topical therapy containing a solution of 0.7% cantharidin in a proprietary single-use applicator, in subjects with up to six warts. In both cohorts, VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable warts at Day 84 and the secondary endpoint of the percentage reduction of warts. VP-102 was well-tolerated with no serious adverse events reported.

"This is exciting news for Verrica and our proprietary cantharidin product. Positive Phase 2 data of VP-102 for the treatment of common warts, after the successful Phase 3 results achieved with VP-102 for molluscum contagiosum, further increases our confidence in the broad clinical utility and large market potential of our lead product," said Ted White, President and Chief Executive Officer of Verrica. "We are progressing the development of VP-102 for a broad range of skin diseases. We intend to request an 'End of Phase 2' meeting with the FDA for the treatment of common warts, and remain on track to submit an NDA for the treatment of molluscum contagiosum later this year."

Study Results:

The COVE-1 Phase 2 open label clinical study included two cohorts that evaluated the safety and efficacy of VP-102 in subjects with up to six warts. Cohort 1 was conducted at a single site with 21 subjects age 2 years and older receiving up to 4 treatments with VP-102 at least 14 days between treatments with longer treatment intervals allowed at the discretion of the investigator depending on a specific subject's clinical response. While the study was ongoing, Verrica amended the protocol to allow varying treatment intervals in Cohort 1 at the discretion of the investigator in order to identify the optimal treatment dosing regimen and added a second cohort to the study.

Cohort 2 was conducted at four sites with 35 subjects age 12 years and older receiving up to 4 treatments with VP-102 every 21 days. Paring of warts, a technique commonly used by dermatologists to prepare the wart for treatment, was allowed in Cohort 2 to remove any adherent thick scale from a wart prior to application of study drug. The primary analysis was conducted at Day 84 with an additional period of follow-up through Day 147. Topline analysis included data from the assessment of warts at study visits over 12 weeks. Results showed 51% of subjects (18 of 35) treated with VP-102 in Cohort 2 achieved complete clearance of all treatable warts at Day 84. Secondary endpoints included the percent change from baseline in the number of treatable warts and VP-102 achieved a 51% reduction in the number of warts (28 of 55 warts) compared to baseline by Day 84.

Consistent with the results from the Phase 3 clinical trials in molluscum, VP-102 was also well-tolerated with side effects that were primarily mild-to-moderate. The most frequently reported adverse events were application site reactions that are well-known, reversible side effects related to the mechanism of action of cantharidin, a blistering agent, which is the active ingredient in VP-102. There were no serious adverse events reported.

"Behind acne, warts are the most common dermatological complaint and our treatment options are limited as there are no FDA-approved treatments," said Scott T. Guenthner, MD, FAAD, founder of the Dermatology Center of Indiana and lead investigator for the COVE-1 study. "Further, common warts are very persistent and difficult to treat, which is frustrating to patients. The data results on the complete clearance of treatable warts and the percentage of wart reduction in this Phase 2 study is very meaningful and highlight the potential of VP-102 as an important new option for people with common warts."

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 common warts, Verrica plans to submit this data for presentation at future medical meetings and for publication in a peer-reviewed medical journal.

Verrica Conference Call

Management will conduct a conference call at 8 a.m. ET tomorrow, June 27, 2019, to discuss the results. The conference call will be webcast and can be accessed by logging on to the “Investors” section of the Verrica website, www.verrica.com, prior to the event.

The webcast will also be available via the following link: https://edge.media-server.com/m6/p/ju8namrg. A replay of the webcast will be archived on the Company’s website for 30 days following the call.

To participate on the live call, please dial 866-688-9534 (domestic) or 409-216-0837 (international), and reference conference ID 7183118 prior to the start of the call.

About Common Warts

Common warts (verruca vulgaris) are skin growths caused by a contagious viral skin infection, most commonly on the fingers or hands. The human papilloma virus (HPV), the causative agent in common warts, is transmitted by touch. The virus enters the skin and causes skin growths by inducing the skin cells to multiply rapidly. Common warts are benign, but treatment is recommended to prevent the spread of infection and relieve the patient’s physical and psychological discomfort.

About Verrica Pharmaceuticals Inc.

Verrica Pharmaceuticals Inc. 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, a New Drug Application for VP-102 for the treatment of molluscum is planned for the second half of 2019. 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. An additional Phase 2 trial is planned in external genital warts. A second product candidate, VP-103, is in pre-clinical development for plantar warts. For more information, visit www.verrica.com.

Cautionary Note Regarding 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 further advancement of VP-102 for the treatment of common warts, submission of a NDA in the second half of 2019 for VP-102 for the treatment of molluscum and the large market potential of VP-102. 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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