



Verrica Announces Successful Phase 2 Innovate Trial and Complete Enrollment of Phase 3 Trials of VP-102 in Molluscum Contagiosum Ahead of Schedule

September 12, 2018

Innovate trial results reaffirm Phase 3 protocol design

No serious adverse events (SAEs) reported during the Innovate trial

Phase 3 pivotal trials for molluscum contagiosum fully enrolled and topline results now expected in 1Q 2019

WEST CHESTER, Pa., Sept. 12, 2018 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (Verrica) (Nasdaq: VRCA), a pharmaceutical company focused on identifying, developing and commercializing innovative pharmaceutical products for the treatment of skin diseases with significant unmet needs, today announced positive results from its Phase 2 Innovate clinical trial of VP-102 (study VP-102-103). VP-102 is a proprietary drug-device combination containing a novel topical solution of 0.7% cantharidin currently under development for the treatment of molluscum contagiosum (molluscum). Verrica also announced the early completion of enrollment for its Phase 3 pivotal trials for molluscum with topline results now expected in the first quarter of 2019.

Innovate is an open label, single-center trial with the primary objective to determine any potential systemic exposure from a single 24-hour dermal application of VP-102 when applied to molluscum lesions on pediatric subjects 2 years of age and older. The trial enrolled 33 subjects into either the exposure group (n=17) or the standard group (n=16) with 32 subjects completing the trial. Following an initial treatment of all subjects with VP-102 and a 21-day evaluation period, treatment continued once every 21 days for three additional applications allowing further evaluation of safety, efficacy and impact on quality of life.

Systemic exposure was negligible, as indicated by plasma drug levels that were below the limits of quantification in 65 of 66 samples which were taken either pre-dose or post-dose at timepoints of 2, 6 and 24 hours after treatment with VP-102. One sample was above the limit of quantification at 2 hours after VP-102 treatment, but systemic exposure was not detectable at the 6-hour and 24-hour timepoints in this subject. At the end of trial visit (Week 12), there was a median reduction in molluscum lesions of 98% compared to baseline across all subjects enrolled in the Innovate trial and 50% of subjects who completed the trial experienced complete clearance of their treatable molluscum lesions. The safety profile observed during the trial was favorable overall and no SAEs were reported.

"We were pleased to observe a favorable safety profile of VP-102 and clinically meaningful efficacy as assessed by complete clearance and substantial reduction in molluscum lesion counts over a 12-week period," stated Patrick Burnett, M.D., Ph.D., Chief Medical Officer of Verrica. "The complete clearance rate for the Innovate trial exceeds the assumptions for powering in the current VP-102 Phase 3 clinical trials and reaffirms our confidence in the ongoing Phase 3 program."

Additionally, Verrica announced the earlier than expected completion of enrollment of its Phase 3 clinical trials, CAMP-1 (study VP-102-101) and CAMP-2 (study VP-102-102), two randomized, double-blind, multicenter, placebo-controlled trials of VP-102 for the treatment of molluscum. The primary objective of the trials is to evaluate the efficacy of dermal application of VP-102 relative to placebo, when treated once every 21 days for up to four applications, by assessing the proportion of subjects achieving complete clearance of all treatable molluscum lesions at day 84 (visit 5).

"The rate in which we enrolled our Phase 3 pivotal trials speaks to the significant underserved patient population," commented Ted White, President and Chief Executive Officer of Verrica. "We remain committed to making VP-102 the standard of care for the treatment of molluscum, a disease with currently no FDA-approved treatments, and look forward to reporting our pivotal topline results in the first quarter of next year."

About Molluscum Contagiosum

Molluscum contagiosum, or molluscum, is a highly contagious, primarily pediatric, common skin disease caused by a pox virus that produces multiple raised flesh-colored papules, or skin lesions. Molluscum typically presents with 10 to 30 lesions and can present with over 100 lesions. If left untreated, molluscum lesions persist for an average of 13 months with some cases remaining unresolved for more than two years. There are currently no approved drugs for molluscum.

About VP-102

Verrica is currently advancing its lead product VP-102, a proprietary topical drug device combination therapy containing a novel topical solution of 0.7% cantharidin, for the treatment of molluscum and verruca vulgaris (common warts). Verrica is also currently evaluating and prioritizing other potential indications for VP-102 and the company's proprietary topical solutions of cantharidin.

About Verrica Pharmaceuticals Inc.

Verrica is a pharmaceutical company focused on identifying, developing and commercializing innovative pharmaceutical products for the treatment of skin diseases with significant unmet needs. The company's lead product candidate, VP-102, is currently being evaluated in two Phase 3 clinical trials for the treatment of molluscum and in a Phase 2 clinical trial for the treatment of common warts.

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 clinical development of Verrica's product candidates and the availability of data from Verrica's clinical trials, including the timing of topline results from the Phase 3 pivotal trials for 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 conduct of clinical trials, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, filed with the U.S. Securities and Exchange Commission (SEC) on August 7, 2018, and Verrica's other Periodic Reports filed with the SEC. 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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Source: Verrica Pharmaceuticals Inc.