# Verrica Achieves Positive Topline Results from Two Pivotal Phase 3 Clinical Trials of VP-102 in Patients with Molluscum Contagiosum

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*CAMP-1 and CAMP-2 Phase 3 pivotal trials for molluscum contagiosum both achieve statistical significance for the primary endpoint with p-values less than 0.0001*

*No serious adverse events in VP-102 treated subjects*

*Verrica to submit a Section 505(b)(1) New Drug Application (NDA) in 2H 2019*

*No FDA approved treatments are currently available for molluscum contagiosum, a highly contagious, primarily pediatric, common skin disease affecting an estimated 6 million people in the United States*

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

WEST CHESTER, Pa., Jan. 03, 2019 (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 topline results from its Phase 3 CAMP-1 and CAMP-2 pivotal trials with VP-102 for the treatment of molluscum contagiosum (molluscum). Molluscum is a highly contagious skin disease affecting primarily children, with no current FDA approved treatment. Both clinical trials evaluated the safety and efficacy of VP-102, a proprietary drug-device combination containing a novel topical solution of 0.7% cantharidin, compared to placebo. In each trial, VP-102 exhibited a clinically and statistically significant proportion of subjects demonstrating complete clearance of all treatable molluscum lesions versus placebo. VP-102 was well-tolerated in both trials, with no serious adverse events reported in VP-102 treated subjects.

“The topline results from CAMP-1 and CAMP-2 validate our platform and bring us one step closer to our goal of providing patients with the first FDA approved treatment for molluscum contagiosum, a significantly undertreated skin disease affecting an estimated 6 million people in the United States,” commented Ted White, President and Chief Executive Officer of Verrica. “We believe the efficacy and safety profiles of VP-102 observed in these two trials provide a strong foundation for our U.S. NDA which we intend to submit in the second half of this year.”

The Phase 3 program for molluscum consisted of two clinical trials, CAMP-1 (study VP-102-101) and CAMP-2 (study VP-102-102). The two trials, identical in design, were randomized, double-blind, multicenter, placebo-controlled trials of VP-102 for the treatment of molluscum. CAMP-1 was conducted under an FDA Special Protocol Assessment (SPA). The primary objective of the trials was 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 (Week 12/End of Study visit). Secondary endpoints included the proportion of subjects with complete clearance at study visits on Days 21 (Week 3), 42 (Week 6) and 63 (Week 9).

CAMP-1 and CAMP-2 enrolled 528 subjects in total and were conducted at 31 centers in the United States. The trials evaluated the safety and efficacy of VP-102 compared to placebo in subjects 2 years of age and older with molluscum contagiosum. Complete clearance was evaluated through assessment of lesion number at study visits over 12 weeks. Results from CAMP-1 and CAMP-2 showed 46% and 54% of subjects treated with VP-102, respectively, achieved complete clearance of all treatable molluscum lesions 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 the number of molluscum lesions, a pre-specified endpoint, in CAMP-1 and CAMP-2, respectively, compared to 20% and 19% for subjects on placebo.

“Molluscum contagiosum can often have a negative impact on the quality of life of affected children, exacerbated by the skin irritation and inflammation that can result as complications of the disease. The high lesion clearance rate demonstrated at Day 84 for VP-102 compared to placebo in the Phase 3 trials is clinically significant and could potentially position VP-102 to become the standard of care for treating molluscum,” stated Lawrence Eichenfield, M.D., Chief of Pediatric and Adolescent Dermatology at Rady Children’s Hospital-San Diego and lead investigator for the VP-102 Phase 3 molluscum program.

Additional CAMP-1 Results

- The proportion of subjects achieving complete clearance at Week 9 (Day 63), a secondary endpoint, was 32% of subjects compared to 17% of placebo treated subjects ($p=0.007$).
- The proportion of subjects achieving complete clearance at Week 6 (Day 42), a secondary endpoint, was 21% of subjects compared to 9% of placebo treated subjects ($p=0.015$).

- The proportion of subjects achieving complete clearance at Week 3 (Day 21), a secondary endpoint, was 11% of subjects compared to 4% of placebo treated subjects (p=0.030). VP-102 demonstrated superiority over placebo with only one application of study drug.
- In this trial, 160 subjects were randomized to receive VP-102 and 106 subjects were randomized to receive placebo. Of the subjects enrolled in the trial, 150 (94%) patients who received VP-102 completed the study, compared to 100 (94%) placebo treated subjects.

Additional CAMP-2 Results

- The proportion of subjects achieving complete clearance at Week 9 (Day 63), a secondary endpoint, was 28% of subjects compared to 5% of placebo treated subjects (p<0.0001).
- The proportion of subjects achieving complete clearance at Week 6 (Day 42), a secondary endpoint, was 13% of subjects compared to 4% of placebo treated subjects (p=0.010).
- The proportion of subjects achieving complete clearance at Week 3 (Day 21), a secondary endpoint, was 5% of subjects compared to 2% of placebo treated subjects (p=0.138).
- In this trial, 150 subjects were randomized to receive VP-102 and 112 subjects were randomized to receive placebo. Of the subjects enrolled in the trial, 139 (93%) subjects who received VP-102 completed the study, compared to 108 (96%) placebo treated subjects.

Consistent with the results from the Phase 2 clinical trials, VP-102 was also well-tolerated in the Phase 3 trials, 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 treatment-related serious adverse events reported in CAMP-1 or CAMP-2.

The most frequently reported adverse events in the CAMP-1 trial (>10% in either group) were application site vesicles (81% and 25% for VP-102 and placebo, respectively), application site pain (59% and 14%), application site pruritus (55% and 30%), application site erythema (33% and 18%), application site scab (31% and 17%), application site discoloration (25% and 8%) and application site dryness (13% and 5%). Five subjects (3%) in the VP-102 group and no placebo subjects discontinued due to an adverse event.

The most frequently reported adverse events in the CAMP-2 trial (>10% in either group) were application site vesicles (94% and 30% for VP-102 and placebo, respectively), application site scab (57% and 20%), application site pain (55% and 14%), application site erythema (47%% and 25%), application site pruritus (43% and 33%), application site discoloration (31% and 8%) and application site dryness (26% and 18%). One subject each in the VP-102 and placebo groups (<1% each) discontinued due to an adverse event.

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 today 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/jka6gazi**. 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 6174215 prior to the start of the call.

**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 Molluscum Contagiosum**

Molluscum contagiosum, or molluscum, is a highly contagious, primarily pediatric, common skin disease affecting an estimated 6 million people in the United States 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 FDA approved drugs for molluscum.

**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. Verrica is headquartered in West Chester, PA. For more information, please 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 timing of the planned submission of a new drug application for VP-102, the potential regulatory approval of VP-102 and the development of VP-102 indications in addition to 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, and other risks and uncertainties that are described in Verrica's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 and Verrica's other periodic reports filed 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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