Verrica Pharmaceuticals Provides Regulatory Update on VP-102

June 29, 2020

WEST CHESTER, Pa., June 29, 2020 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (“Verrica”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for viral skin diseases requiring medical interventions, today announced that, on June 24, 2020, the Company received a letter from the U.S. Food and Drug Administration (FDA) as part of the FDA’s ongoing review of the Company’s New Drug Application (NDA) for VP-102 (cantharidin 0.7% topical solution), Verrica’s lead product candidate for the treatment of molluscum contagiosum. The letter states that there are deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time. The letter further states that the notification does not reflect a final decision on the information under review. In a letter dated November 26, 2019, the FDA had assigned a Prescription Drug User Fee Act (“PDUFA”) goal date of July 13, 2020 for completion of its review of the NDA.

The FDA’s letter does not identify any specific items. But, the Company notes that information requests from the FDA during the NDA review have focused on CMC aspects of the drug-device combination. Verrica’s ability to address these CMC-related requests, however, was significantly impacted in large part by the COVID-19 pandemic.

The requests include, but are not limited to, a specific request related to a potential safety issue with the applicator that could arise if the instructions for use were not properly followed. In response, the Company incorporated an additional user feature into the applicator to address that issue. The addition of that user feature, however, has affected human factors testing as well as requiring additional supportive stability data on the fully assembled device incorporating such feature. The Company believes that both its long-term and registration stability data with the ampule, and the as-submitted applicator, support significant shelf life and stability for VP-102.

The Company anticipates interactions with, and additional communication from, the FDA and intends to work with the FDA to resolve and address any items as quickly as possible.

Notwithstanding the pandemic or the CMC-related requests that have arisen during the review cycle, the Company believes that the positive results from its 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 indicates that VP-102 remains viable for FDA approval.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for viral skin diseases requiring medical interventions. The Company’s late-stage product candidate, VP-102, is a potential first-in-class topical therapy for the treatment of molluscum contagiosum. An NDA for VP-102 for the treatment of molluscum is currently under review by FDA and, if approved, VP-102 will be marketed in the United States under the conditionally accepted brand name YCANTH™. Verrica intends to initiate a Phase 3 program of VP-102 for the treatment of common warts when conditions are appropriate, given the COVID-19 pandemic. In addition, VP-102 is being evaluated in Phase 2 study for the treatment of external genital warts. The Company is also developing VP-103, its second cantharidin-based product candidate, and intends to launch a Phase 2 study in subjects with plantar warts when conditions are appropriate. 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 receipt and timing of the FDA’s approval of the NDA, the Company’s expectations with regard to its interactions and communications with the FDA, plans and expectations related to the PDUFA date, the potential benefits and potential approval and commercialization of YCANTH™ for the treatment of molluscum, and the clinical development of product candidates for additional indications, including common warts, external genital warts and plantar warts. 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 March 31, 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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