Verrica Receives Complete Response Letter from the FDA for its NDA for VP-102 as a Direct Result of Deficiencies at General Reinspection of Sterling Pharmaceuticals Services, LLC

May 25, 2022

Verrica has been advised that PAI (Pre-Approval Inspection) was conducted at Sterling and is not aware of any reported observations related to the PAI of VP-102 operations

Review Division had advised Verrica that the review of NDA was completed and label was ready to be communicated, except for Sterling's classification status

Verrica has been notified that Sterling is on OAI (Official Action Indicated) status

WEST CHESTER, Pa., May 24, 2022 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (Verrica) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding its New Drug Application (NDA) for VP-102 for the treatment of molluscum contagiosum (molluscum).

The only deficiency listed in the CRL was related to the deficiencies identified at a general reinspection of Sterling Pharmaceuticals Services, LLC (Sterling), the contract manufacturing organization (CMO) that manufactures Verrica's bulk solution drug product. Sterling advised Verrica on May 20, 2022 that it received notice that it is on OAI status. Sterling's OAI classification resulted from a week-long reinspection of the CMO conducted by FDA in February 2022. The reinspection was conducted approximately 90 days after Sterling was originally classified by the Agency as VAI (Voluntary Action Indicated) on November 17, 2021. Verrica understood that the VAI classification did not indicate that a reinspection was required.

The CRL did not identify any other deficiencies. Moreover, none of the issues identified by FDA during the reinspection were specific to the manufacturing of VP-102. Additionally, Verrica was informed by the Division that it had completed its review of Verrica's NDA and product label, there were no open questions on the NDA review, and the VP-102 label was ready to be communicated. However, Verrica has been informed that internal FDA policy is preventing the Agency from communicating the label and approving the NDA when a CMO has an unresolved classification status or is placed on OAI status.

"Based on the successful PAI of VP-102 at Sterling and our understanding that the Division was ready to communicate our label, we believe our NDA meets the statutory standards for approval and that any issues at Sterling do not impact the manufacturing, quality, efficacy, or safety of VP-102," commented Ted White, Verrica's President and Chief Executive Officer. "However, we recognize that the Dermatology Division's hands may be tied due to the reinspection issues at Sterling and thank them for their efforts working with us to date." In addition, Mr. White noted that "VP-102 is a non-sterile topical dermatology product that is not systemically absorbed. It is completely solvent based and has been demonstrated to have bactericidal and viricidal properties. By comparison, the observations cited at Sterling which led to its OAI classification status were predominantly related to its distinct sterile operations where higher-risk, sterile ophthalmic products are manufactured by Sterling for, among other distributors, the U.S. government."

For additional quality control and oversight at Sterling, Verrica proactively and responsibly maintains a Person in the Plant policy which requires qualified Verrica personnel be present at Sterling whenever VP-102 is manufactured to ensure Verrica's product is in strict compliance with the validated process and cGMP. In addition, Verrica independently tests the drug product manufactured at Sterling on two separate occasions at Alcami Laboratories (Alcami) after manufacturing at Sterling has been completed. First, the bulk solution is tested by Alcami after it is packaged into ampules. Then, it is tested again by Alcami after the ampules are assembled into finished VP-102 applicators.

The FDA previously issued a CRL for Verrica's NDA for VP-102 on September 16, 2021, citing, in part, a deficiency related to the Agency's general inspection of Sterling; likewise, not specifically related to the manufacturing of VP-102. Following the CRL, the FDA classified Sterling as VAI. The Establishment Inspection Report (EIR) issued on November 17, 2021 in connection with the VAI specifically stated that (i) FDA would not take or recommend regulatory or enforcement action against Sterling, (ii) the VAI classification would not directly negatively impact FDA's assessment of any pending marketing application referencing Sterling, and (iii) approval of an application may depend on a PAI.

Based on the VAI classification of Sterling and the statements contained in the EIR, Verrica was led to believe that any concerns at Sterling had been resolved to FDA's satisfaction, and as specifically required in the CRL for approval of its NDA. Accordingly, Verrica resubmitted its NDA on November 24, 2021, which was accepted.

The NDA submission was based on positive results from two identical Phase 3 randomized, double-blind, multicenter clinical trials (CAMP-1 and CAMP-2) that evaluated the safety and efficacy of VP-102 compared to placebo in a combined 500 subjects two years of age and older diagnosed with molluscum. In both trials, a clinically and statistically significant number of patients treated with VP-102 met the primary endpoint of complete

clearance of all treatable molluscum lesions at the end of the trial. VP-102 was well-tolerated in both trials treating nearly 8,000 lesions with bulk solution manufactured at Sterling, with no serious adverse events reported and a dropout rate of less than two percent.

Mr. White stated that “Verrica is extremely disappointed in the Agency’s issuance of the CRL under the totality of these circumstances. However, as Verrica weighs all its options to bring the first FDA-approved treatment for molluscum, one of the largest unmet needs in dermatology, to the market as soon as possible, it will continue to work collaboratively with the Agency.” Verrica currently intends to file a Type A meeting request by the end of this week.

In the meantime, Verrica is working collaboratively with Sterling and its regulatory and quality consultants to help Sterling present multiple options to the Agency to allow Sterling to expeditiously satisfy the majority of the deficiencies resulting in its OAI classification and which are the basis for the CRL. Concurrently, Verrica is engaging an additional CMO to serve as an alternative supplier of VP-102’s bulk solution.

PBM Capital has expressed its continued support of the company, and based on these discussions, Verrica is confident that it will have access to adequate capital to fund operations through the potential approval of VP-102 for molluscum.

About VP-102

Verrica’s lead product candidate, VP-102, is a proprietary drug-device combination product that contains a GMP-controlled formulation of cantharidin (0.7% w/v) delivered via a single-use applicator that allows for precise topical dosing and targeted administration. VP-102 could potentially be the first product approved by the FDA to treat molluscum contagiosum — a common, highly contagious skin disease that affects an estimated six million people in the United States, primarily children. 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.

About Molluscum Contagiosum (Molluscum)

There are currently no FDA-approved treatments for molluscum, a highly contagious viral skin disease that affects approximately six million people — primarily children — in the United States. Molluscum is caused by a pox virus that produces distinctive raised, skin-toned-to-pink-colored lesions that can cause pain, inflammation, itching and bacterial infection. It is easily transmitted through direct skin-to-skin contact or through fomites (objects that carry the disease like toys, towels or wet surfaces) and can spread to other parts of the body or to other people, including siblings. The lesions can be found on most areas of the body and may carry substantial social stigma. Without treatment, molluscum can last for an average of 13 months, and in some cases, up to several years.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica’s late-stage product candidate, VP-102, is in development to treat molluscum, common warts and external genital warts, three of the largest unmet needs in medical dermatology. Verrica is also developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. The Company has also entered a worldwide license agreement with Lytix Biopharma AS to develop and commercialize LTX-315 for dermatologic oncology conditions. For more information, visit www.verrica.com.

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,” “look forward,” and similar expressions, and are based on Verrica’s current beliefs and expectations. These forward-looking statements include expectations regarding Verrica’s expectations with regard to requesting a Type A meeting with the FDA, and the potential approval of the NDA for VP-102 and the potential benefits and potential commercialization of VP-102 for the treatment of molluscum, if approved, Verrica’s ability to access adequate capital to fund its operations through the potential approval of VP-102 for molluscum, Sterling’s ability to expeditiously satisfy the majority of the deficiencies resulting in its OAI classification, and Verrica’s ability to enter into a definitive agreement with an additional CMO. 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, 2021 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.

FOR MORE INFORMATION, PLEASE CONTACT:

Investors:

Terry Kohler
Chief Financial Officer
info@verrica.com

William Windham
Solebury Trout
646.378.2946
wwindham@soleburytrout.com

Media:

Zara Lockshin
Solebury Trout
646.378.2960

zlockshin@soleburytrout.com

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