Verrica Pharmaceuticals Announces Amendment to Company's Collaboration and License Agreement with Torii Pharmaceutical Co. Ltd. to Fund Global Pivotal Phase 3 Clinical Trial to Study YCANTH® for the Treatment of Common Warts

May 15, 2024 at 7:30 AM EDT

Global pivotal Phase 3 clinical trial would be conducted jointly by Verrica and Torii Pharmaceutical; trial expected to begin in the 1st half of 2025

Amendment should benefit both parties from a cost and time to market standpoint; funding structure is expected to have a minimal impact on Verrica's cash position

Common warts is one of the largest and most underserved patient populations in medical dermatology with a prevalence of ~22M in the U.S. and no FDA approved products; Verrica believes common warts represents a multibillion-dollar commercial opportunity; patient opportunity for common warts in the E.U. is believed to be at least equivalent to the U.S.

WEST CHESTER, Pa., May 15, 2024 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. ("Verrica" or "the Company") (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, today announced that it has entered into an amendment to its existing licensing agreement with Torii Pharmaceutical Co. Ltd. (Torii), to jointly conduct a global pivotal Phase 3 clinical trial of YCANTH® for the treatment of common warts.

"We are pleased to announce this significant amendment to our license agreement with Torii Pharmaceutical to advance YCANTH into a global pivotal Phase 3 clinical trial for the treatment of common warts," said Ted White, President and Chief Executive Officer of Verrica Pharmaceuticals. "Torii has been an outstanding partner in the development of YCANTH for molluscum contagiosum, and we look forward to our continued collaboration to progress YCANTH through a pivotal global Phase 3 clinical trial for common warts, which represents the single largest and most underserved patient population in all of dermatology. If positive, the data from this global Phase 3 clinical trial would not only potentially allow Verrica to submit a sNDA in the U.S. seeking FDA approval for the use of YCANTH for the treatment of common warts, but may also be utilized by Verrica to seek future marketing authorizations in territories outside the U.S. and Japan, including potentially within the European Union."

In March 2021, Verrica and Torii Pharmaceutical entered into an agreement granting Torii an exclusive license to develop and commercialize Verrica's product candidates for the treatment of molluscum contagiosum and common warts in Japan, including YCANTH (TO-208 in Japan). The terms of the amendment would enable the two parties to equally split the cost of the global Phase 3 clinical trial in common warts, with Torii funding Verrica's portion of the costs as an offset to Torii's future payment obligations to Verrica based on regulatory milestones and sales of YCANTH for molluscum contagiosum and common warts in Japan. In addition, Torii would make a milestone payment of $8 million to Verrica upon the first patient dosed in Japan in the Phase 3 clinical trial. Initiation of the global study remains subject to feedback from the U.S. FDA and Japan's Pharmaceuticals and Medical Device Agency (PMDA) on the proposed design of the Phase 3 clinical trial.

With a prevalence of approximately 22 million patients in the U.S. alone and no FDA approved therapies, common warts represent one of the largest unmet needs in all of dermatology, which Verrica believes represents a multibillion-dollar commercial opportunity. In the United States, approximately 50% of the patients who seek treatment for common warts are children. If YCANTH is successfully developed, approved and commercialized for the treatment of common warts, Verrica anticipates a high degree of call point overlap and marketing synergies with its molluscum promotion of YCANTH. Verrica further believes that the common wart patient opportunity in the European Union is at least as large as that in the United States.

COVE-1 Phase 2 Data in Common Warts

Verrica has previously announced positive results from the Phase 2 COVE-1 clinical trial that evaluated YCANTH (VP-102) for the treatment of common warts. COVE-1 was an open label clinical trial that evaluated the safety and efficacy of VP-102 in two cohorts of subjects with up to six warts. 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 that 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.

About YCANTH (formerly VP-102)

YCANTH is a proprietary drug-device combination product that contains a GMP-controlled formulation of cantharidin delivered via a single-use applicator that allows for precise topical dosing and targeted administration for the treatment of molluscum. YCANTH is currently approved by the FDA to treat molluscum in adult and pediatric patients 2 years of age and older, a common, highly contagious viral skin disease that affects an estimated six million people in the United States, primarily children. Please visit YCANTHPro.com for additional information.

In addition, Verrica has successfully completed a Phase 2 clinical trial of VP-102 for the treatment of common warts and a Phase 2 clinical trial of VP-102 for the treatment of external genital warts.

YCANTH should only be administered by a trained healthcare professional. YCANTH is not for home use.

Important Safety Information

CONTRAINDICATIONS:

None.

WARNINGS AND PRECAUTIONS:

- YCANTH is for topical use only. YCANTH is not for oral, mucosal, or ophthalmic use. Life threatening or fatal toxicities can occur if YCANTH is administered orally. Avoid contact with the treatment area, including oral contact, after treatment. Ocular toxicity can occur if YCANTH comes in contact with eyes. If YCANTH gets in eyes, flush eyes with water for at least 15 minutes.
- Local Skin Reactions: Reactions at the application site may occur, including vesiculation, pruritus, pain, discoloration, and erythema. Avoid application near eyes and mucosal tissue, and to healthy skin. If YCANTH contacts any unintended surface, or healthy skin, immediately remove. If severe local skin reactions occur, remove prior to the recommended 24 hours after treatment.
- YCANTH is flammable, even after drying. Avoid fire, flame or smoking near lesion(s) during treatment and after application until removed.

ADVERSE REACTIONS:

The most common (incidence ≥1%) reactions are the following local skin reactions at the application site: vesiculation, pain, pruritus, scabbing, erythema, discoloration, application site dryness, edema, and erosion. Local skin reactions at the application site were observed in 97% of subjects treated with YCANTH during clinical trials. These local skin reactions are expected and related to the anticipated blistering response of the skin to cantharidin.

DRUG INTERACTIONS:

No studies evaluating the drug interaction potential of cantharidin have been conducted.

USE IN SPECIFIC POPULATIONS:

Pregnancy: There are no available data with use of YCANTH in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. Given that systemic exposure to cantharidin following topical administration is low, maternal use is not expected to result in fetal exposure to the drug.

Lactation: Avoid application of YCANTH topical solution to areas with increased risk for potential ingestion by or ocular exposure to the breastfeeding child.

OVERDOSAGE:

Oral ingestion of cantharidin has resulted in renal failure, blistering and severe damage to the gastrointestinal tract, coagulopathy, seizures, and flaccid paralysis.

Please see accompanying full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact Verrica Pharmaceuticals Inc. at 1-877-VERRICA (1-877-837-7422), or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. Local skin reactions are expected and should be reported if they are severe.

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 is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica's product YCANTH (cantharidin), is the first and only commercially available treatment approved by the FDA to treat adult and pediatric patients two years of age and older with molluscum contagiosum, a highly contagious viral skin infection affecting approximately 6 million people in the United States, primarily children. VP-102 is also in development to treat common warts and external genital warts, two of the largest remaining unmet needs in medical dermatology. Verrica is developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. Verrica has also entered a worldwide license agreement with Lytix Biopharma AS to develop and commercialize VP-315 (formerly LTX-315 and VP-LTX-315) for non-melanoma skin cancers including basal cell carcinoma and squamous cell carcinoma. 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 the Company’s expectations with regard to the clinical development and potential regulatory approval of and commercialization of YCANTH™ for the treatment of common warts in the United States and Japan, including Verrica’s expectations regarding the timing of the initiation of a Phase 3 clinical trial of YCANTH™ (VP-102) for the treatment of common warts, and the potential to seek marketing authorizations outside of the United States and Japan. 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, 2023, 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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Source: Verrica Pharmaceuticals Inc.