



## Verrica Issues Statement in Support of FDA's Warning Letters to Manufacturers and Retailers for Producing and Selling Unapproved Products for the Treatment of Molluscum Contagiosum

*Verrica's product YCANTH™ is the first and only FDA-approved treatment for molluscum, a highly contagious viral skin infection affecting approximately 6 million people annually in the United States, primarily children*

*YCANTH™ is expected to be available for commercial use by licensed healthcare providers by September 2023*

WEST CHESTER, PA –August 23, 2023 (GLOBE NEWSWIRE) – Verrica Pharmaceuticals Inc. (“Verrica” or “the Company”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for skin diseases requiring medical interventions, issued a statement today in support of the U.S. Food and Drug Administration’s (“FDA’s”) recent action against retailers and manufacturers of unapproved products for the treatment of molluscum contagiosum.

“On the heels of the June 1, 2023 FDA warning to consumers not to use unapproved products for the treatment of molluscum contagiosum, we are pleased the FDA is taking additional measures against these unapproved products,” said Ted White, President and Chief Executive Officer of Verrica Pharmaceuticals. “It is clear that the FDA views molluscum as a serious health problem that requires medical intervention with therapies that have been rigorously tested and properly reviewed. Verrica has conducted two Phase 3 trials to demonstrate the clinical safety and efficacy of YCANTH™, so that the millions of people, primarily children, who suffer from this viral infection can finally receive a safe, effective, and FDA-approved treatment for their condition.”

### **About Molluscum Contagiosum (Molluscum)**

Molluscum is 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 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 the only product approved by the FDA to treat molluscum — a

common, highly contagious skin disease that affects an estimated six million people in the United States, primarily children.

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.

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

### **Indication**

YCANTH (cantharidin) topical solution, 0.7% is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older.

### **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 vesication, 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  $\geq 1\%$ ) reactions are the following local skin reactions at the application site: vesication, 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](http://www.fda.gov/medwatch). Local skin reactions are expected and should be reported if they are severe.**

**About Verrica Pharmaceuticals Inc.**

Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. On July 21, 2023, Verrica's lead product, YCANTH™ (cantharidin), became the first treatment approved by the FDA to treat pediatric and adult patients 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 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 dermatologic oncology conditions. For more information, visit [www.verrica.com](http://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," and similar expressions, and are based on Verrica's current beliefs and expectations. These forward-looking statements include expectations regarding the commercial launch of YCANTH and the potential benefits of potential benefits of YCANTH and Verrica's product candidates to patients. 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 uncertainties that are described in Verrica's Annual Report on Form 10-K for the year ended December 31, 2022, Verrica's Quarterly Report on Form 10-Q for the quarter ended June 30, 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.

**FOR MORE INFORMATION, PLEASE CONTACT:**

Investors:

**Terry Kohler**

Chief Financial Officer

[tkohler@verrica.com](mailto:tkohler@verrica.com)

**Kevin Gardner**

LifeSci Advisors

[kgardner@lifesciadvisors.com](mailto:kgardner@lifesciadvisors.com)

**Chris Calabrese**

LifeSci Advisors

[ccalabrese@lifesciadvisors.com](mailto:ccalabrese@lifesciadvisors.com)