Verrica Pharmaceuticals Announces that YCANTH™ Receives New Chemical Entity Status and Orange Book Listing from the FDA

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NCE status provides a minimum of five years of regulatory exclusivity

The Company's U.S. patents and pending patent applications related to YCANTH™ are projected to expire between 2034 and 2041, excluding any patent term adjustment or patent term extension

WEST CHESTER, Pa., March 26, 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 the Company's lead product, YCANTH™, has received New Chemical Entity ("NCE") Status and a listing in the Orange Book from the U.S. Food and Drug Administration ("FDA"), providing a minimum five years of regulatory exclusivity.

"We could not be more pleased to announce YCANTH™ has been granted NCE Status by the FDA," said Ted White, Verrica's President and Chief Executive Officer. "Today's announcement represents the continued execution of our Company's comprehensive intellectual property strategy to maximize the patent and regulatory protections surrounding YCANTH™ and further underscores the product's innovation and intrinsic value in the dermatology market. While NCE status will provide YCANTH™ with a minimum of five years of protection, we anticipate our full patent portfolio to provide protection from generic competition for the next decade and potentially beyond."

Formally described as the Approved Drug Products with Therapeutic Equivalence Evaluations, the Orange Book is an FDA publication that provides a list of drugs approved as safe and effective and also serves as the regulatory resource for information on drug marketing availability, bioequivalence, drug substitution, and patent and exclusivity data.[1] The Orange Book also lists patents covering those drugs, approved methods of their use, and regulatory exclusivities to which they may be entitled.

About Verrica Pharmaceuticals Inc.
Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. On July 21, 2023, YCANTH™ (cantharidin), became the first 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. YCANTH (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," "anticipate", 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 length of time for which YCANTH will not face competition from generic products and patent expiration dates. 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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[1] https://www.fda.gov/media/143766/download

Source: Verrica Pharmaceuticals Inc.