Verrica Pharmaceuticals Announces Presentation of Three Posters Featuring Positive Preliminary Topline Results of VP-315 for the Treatment of Basal Cell Carcinoma at the 2025 Winter Clinical Dermatology Conference

January 21, 2025 at 7:00 AM EST

– Presented data includes a 97% Calculated Objective Response Rate (ORR) of study subjects following treatment with VP-315

– Posters highlight the safety data, tolerability data, and antitumor efficacy data of VP-315 for the treatment of basal cell carcinoma as determined by histological clearance

WEST CHESTER, Pa., Jan. 21, 2025 (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 the presentation of three posters that were presented at the 2025 Winter Clinical Dermatology Conference, which was held from January 17-19, in Miami, Florida. The posters featured clinical data from Part 2 of the Phase 2 study (the "Study") of the Company's novel oncolytic peptide, VP-315, for the treatment of basal cell carcinoma ("BCC").

Verrica presented a poster titled "*Calculated Objective Response Rate (ORR) of 97% from Post-Hoc Analysis of a Phase 2 Multicenter Study to Evaluate the Efficacy of VP-315, an Investigational therapy for Basal Cell Carcinoma (BCC)*" while encore presentations of two additional posters (titled "*Results of a Phase 2 Multicenter Study Evaluating the Safety and Tolerability of VP-315, an Investigational therapy for Basal Cell Carcinoma"* and "Results *of a Phase 2 Multicenter Study to Evaluate the Efficacy of VP-315, an Investigational Therapy for Basal Cell Carcinoma"*) were also made at the conference. The posters included safety and histologic clearance data from 82 patients with up to two target BCC tumors (a total of 91 tumors) in Part 2 of the Study evaluating VP-315 for the treatment of BCC, including patients with tumors on the head and neck.

Part 2 of the Study was designed to explore dosing regimens to help Verrica identify the recommended regimen for a Phase 3 study program. Approximately 51% of tumors treated in the Study achieved complete histological clearance, while those patients with a residual tumor achieved, on average, approximately 71% reduction in tumor size. There were no Treatment Related Serious Adverse Events, and most Treatment Related Adverse Events were mild to moderate.

In the newly-presented poster, Verrica conducted a post-hoc analysis of the data from the Study and announced a Calculated ORR of 97%, defined as the percentage of study subjects who do not demonstrate disease progression and who experience at least a 30% level of tumor reduction along with partial or complete response following treatment The Company still expects genomic and T-cell (immune response) data in the first quarter of 2025 and plans to request an End-of-Phase 2 meeting with the FDA in the first half of 2025 to determine the next steps for the development of VP-315 for the treatment of BCC.

"We remain highly encouraged by the positive preliminary topline results from Part 2 of the Phase 2 study for VP-315, which we believe support a potential change in the treatment paradigm for patients with basal cell carcinoma," said Dr. Jayson Rieger, PhD, MBA, President and Chief Executive Officer of Verrica. "We believe these results will support the use of VP-315 as a potential first line therapy for use in both primary and neoadjuvant settings, and that VP-315 could provide the millions of basal cell carcinoma patients diagnosed in the United States each year with a non-surgical alternative to painful, invasive surgical treatments. We believe that VP-315 could represent a multi-billion-dollar commercial opportunity for Verrica. We look forward to our discussions with the FDA about designing a development path forward for VP-315 in 2025."

About the Phase 2 Study of VP-315
The Study is a 2-part, open-label, multicenter, dose-escalation, proof-of-concept study with a safety run-in designed to assess the safety, pharmacokinetics, and efficacy of VP-315 when administered intratumorally to adults with biopsy-proven BCC. The study enrolled 92 adult subjects with a histological diagnosis of BCC in at least one eligible target tumor. For additional information about this clinical trial, please visit clinicaltrials.gov, identifier NCT05188729.

About VP- 315
VP-315 is a potential first-in-class oncolytic chemotherapeutic peptide immunotherapy administered directly into a tumor to induce immunogenic cell death and thereby unleashing a broad spectrum of tumor antigens for T cell responses, which may offer a non-surgical option for patients suffering from skin cancer. The technology is based on pioneering research in "host defense peptides" – nature's first line of defense towards foreign pathogens. Verrica holds an exclusive worldwide license to develop and commercialize VP-315 for certain dermatologic oncology indications, including non-metastatic melanoma and non-metastatic merkel cell carcinoma, and intends to focus initially on basal cell and squamous cell carcinomas as the lead indications for development. VP-315 has demonstrated positive tumor-specific immune cell responses in multi-indication Phase 1/2 oncology trials.

About Basal Cell Carcinoma

Basal cell carcinoma is the most common form of cancer in the United States, and its incidence is rising worldwide. There are approximately 3-4 million diagnoses of basal cell carcinoma in the U.S. each year, with a high unmet need for new treatment options. Basal cell carcinoma is generally treated with invasive surgery to remove the tumor, which can cause pain, infection, bleeding and scarring.

About Verrica Pharmaceuticals Inc.
Verrica is a dermatology therapeutics company developing medications for skin diseases requiring medical interventions. Verrica's product YCANTH® (VP-102) (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. 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 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 statements concerning the potential of VP-315, the Company's research, development and regulatory plans for VP-315, the timing of the Company's planned clinical trials for VP-315 and reporting data from the Company's clinical trials, and the potential market size opportunity for the treatment of basal cell carcinoma. 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 uncertainties that are described in Vernica's Annual Report on Form 10-K for the year ended December 31, 2023, Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 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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