Veru Announces Scientific Presentations for Novel Prostate Cancer Drug Candidates at the 2019 American Society of Clinical Oncology Genitourinary Cancers Symposium

MIAMI, Feb. 12, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company developing novel medicines for the prostate cancer continuum of care and urology specialty pharmaceuticals, today announced that four presentations relating to Veru drug candidates are being given at the 2019 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium being held February 14-16, 2019 at the Moscone West Building in San Francisco, California.

The presentations have been published online at https://meetinglibrary.asco.org/. Additional information on the meeting can be found on the ASCO Genitourinary Cancers Symposium website: https://gucasym.org/.

Three of the presentations will be about VERU-111, our first-in-class selective oral alpha and beta tubulin inhibitor, which is in a Phase1b/Phase 2 clinical study in 5 clinical sites in the United States. The Phase 1b/2 addresses the large and growing unmet medical need to provide therapies for men who have metastatic castration resistant prostate cancer and who have also become resistant to novel androgen blocking agents (enzalutamide or abiraterone). There are currently no FDA approved drugs approved for this indication.

Presentation Number TPS330, Poster N6

> Presentation Title: Design of Phase 1b/2 study of oral VERU-111, an α and β-tubulin inhibitor, for the treatment of metastatic castration and androgen blocking agent resistant prostate cancer.
> Presenter: Mark Markowski, MD, PhD, Assistant Professor of Oncology, The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
> Session Information: Poster Session A: Prostate Cancer
> Date/Time: February 14, 2019 – 11:30 AM – 1:00 PM and 5:30 PM – 6:30 PM

VERU-111 is currently enrolling an open label Phase1b/2 clinical study in men with metastatic castration prostate cancer who have also failed a novel androgen blocking agent (abiraterone or enzalutamide) and before intravenous taxane chemotherapy (prechemo). The study is being conducted in approximately 15 men in up to 5 clinical sites in the United States. The design of the Phase1b/2 study will be presented at the meeting. The Phase 1 portion will determine both the maximum tolerated dose (safety) and measure effectiveness by measuring serum PSA reductions in approximately 15 men using a standard 3+3 design. The open label Phase 2 clinical study component will enroll an additional 26 men evaluating the VERU-111 dose selected from the Phase 1b study. The primary efficacy endpoint will be the reduction in serum PSA and further assess safety.

Presentation Number 167, Poster G10

> Presentation Title: VERU-111, a novel oral inhibitor of a and b tubulin, inhibits tumor growth in the human castration-resistant AR variant prostate cancer (PCa) model 22Rv1
> Presenter: Mark Markowski, MD, PhD, Assistant Professor of Oncology, The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
> Session Information: Poster Session A: Prostate Cancer
> Date/Time: February 14, 2019 – 11:30 AM – 1:00 PM and 5:30 PM – 6:30 PM

In preclinical studies, oral doses of VERU-111 showed anti-tumor effectiveness in a highly aggressive animal model of human prostate cancer, 22Rv1. Human prostate cancer, 22Rv1 model is similar to the type of metastatic castration resistant prostate cancer affecting the patients enrolling in the Phase 1b/2 study as it is also resistant to androgen blocking agents (abiraterone and enzalutamide). In this preclinical study, oral VERU-111 treatment resulted in significant reductions in prostate cancer tumors and was well tolerated. In contrast, IV taxane chemotherapy with docetaxel did not significantly affect prostate cancer tumor growth and was not as well tolerated as the animals lost weight.

Presentation Number 299, Poster D7

> Presentation Title: The oral a and b tubulin inhibitor, VERU-111, demonstrates no neutropenia, myelosuppression or abnormal liver function in doses being evaluated for the treatment of metastatic castration resistant prostate cancer in nonclinical toxicity studies.
> Presenter: Robert H. Getzenberg, PhD, Executive Associate Dean for Research and Professor of Medicine, Patel College of Medicine, Nova Southeastern University
> Session Information: Poster Session B: Prostate Cancer; Urothelial Carcinoma, Penile, Urethral, Testicular and Adrenal Cancers

Date/Time: February 15, 2019 – 12:15 PM – 1:45 PM and 5:15 PM – 6:15 PM

Taxane chemotherapies, cabazitaxel and docetaxel, are given by intravenous administration once every 3 weeks, and neutropenia, drop in white blood cell count, is the dose limiting toxicity. VERU-111 was given orally each day for 28 days to assess its toxicity in both dogs and rats. VERU-111 was well tolerated and did not result in neutropenia in clinically relevant doses over the 28 days. As an orally administered drug, VERU-111 also did not have any significant changes in liver function tests and bilirubin levels. These safety studies support the possibility of daily dosing of VERU-111 in patients which may allow the oral delivery of more anticancer drug with potentially better safety profile than intravenous taxane chemotherapy.

Presentation Number TPS338, Poster Number N14

Presentation Title: A Phase 2, dose finding, placebo-controlled, study of zuclomiphene citrate to ameliorate the frequency and severity of hot flashes caused by androgen deprivation in men with advanced prostate cancer.
Presenter: Robert H. Getzenberg, PhD, Executive Associate Dean for Research and Professor of Medicine, Patel College of Medicine, Nova Southeastern University
Session Information: Poster Session A: Prostate Cancer
Date/Time: February 14, 2019 – 11:30 AM – 1:00 PM and 5:30 PM – 6:30 PM

The clinical trial design of zuclomiphene citrate (VERU-944), a proprietary oral estrogen receptor agonist drug, will be presented. Zuclomiphene is being evaluated in a placebo controlled, randomized, dose finding (10mg, 50mg, and 100mg versus placebo), multicenter Phase 2 clinical study for the treatment of moderate to severe hot flashes caused by androgen deprivation therapy in men with advanced prostate cancer. Hot flashes are the most common major side effect of androgen deprivation therapy with drugs like LUPRON (leuprolide). Hot flashes not only adversely affect quality of life, but also cause men to consider stopping their cancer treatment for relief of these symptoms. A Phase 2 clinical trial is being conducted in 15 clinical sites in the United States. The primary endpoint is reduction in the frequency of moderate to severe hot flashes at 4 weeks and maintained at 12 weeks compared to baseline. There are no treatments that are FDA approved for this indication.

About VERU-111
VERU-111 is a novel, proprietary, next generation, first-in-class oral selective antitubulin agent that targets and disrupts alpha and beta tubulin subunits of microtubules. In cancer cells, microtubules are critical for transport of growth factor receptors, cellular proliferation, and metastases. In preclinical effectiveness and toxicity studies, orally administered VERU-111 demonstrated significant antitumor activity against castration and novel androgen blocking agent (abiraterone or enzalutamide) resistant human prostate cancers. Furthermore, VERU-111 had significant antitumor effects against cancers that overexpress multidrug resistant proteins, like P-glycoprotein, a common mechanism by which cancer cells become resistant to cancer drugs. At oral doses that had significant antitumor effects, VERU-111 had a favorable safety profile as it did not cause neutropenia or myelosuppression, common dose limiting side effects of other classes of commercially available antitubulins such as intravenous taxanes or intravenous vinca alkaloids.

Veru is conducting an open label Phase1b/2 clinical trial evaluating the safety and effectiveness of VERU-111 in men who have metastatic castration resistant prostate cancer who have also become resistant to novel androgen blocking agents like abiraterone or enzalutamide. In addition to prostate cancer, VERU-111 had antitumor effects in other cancer types including preclinical human models for triple negative breast cancer, ovarian cancer and pancreatic cancer. VERU-111 has the potential to be the first FDA approved selective antitubulin agent that targets and disrupts alpha and beta tubulin subunits of microtubules to treat cancer.

About Zuclomiphene Citrate
Zuclomiphene citrate (VERU-944) is a novel, proprietary, oral, nonsteroidal, estrogen receptor agonist being evaluated in a Phase 2 clinical study to treat hot flashes, one of the most common side effects caused by androgen deprivation therapy (ADT), or hormone treatment for men with advanced prostate cancer. The Phase 2 clinical trial will enroll approximately 120 men in over 15 clinical sites in the United States. Zuclomiphene citrate has the potential to be the first FDA approved drug for hot flashes caused by prostate cancer hormone therapy. It is estimated that there are over 600,000 men in the US on ADT and about 30% of them suffer from moderate to severe hot flashes. Concern over hot flashes make men less likely to begin ADT and can lead to early discontinuation of this effective prostate cancer therapy. Based on an independent market analysis sponsored by the Company, the Company estimates the US market potential for zuclomiphene citrate is over $600 million annually.

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company developing novel specialty pharmaceuticals and medicines for the prostate cancer continuum of care. The Veru prostate cancer pipeline includes

zuclomiphene citrate (also known as VERU-944, *cis*-clomiphene) and VERU-111 (bisindole). Zuclomiphene citrate is an estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agent (abiraterone or enzalutamide) therapies. VERU-111 is being evaluated in men with metastatic refractory prostate cancer in an open label Phase 1b/2 clinical trial.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. The clinical trial of the Company's proprietary Tadalafil and Finasteride Combination tablet (TADFIN™ tablet) met FDA requirements for bioavailability and bioequivalence for the co-administration of tadalafil 5mg and finasteride 5mg dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride (PROSCAR® and PROPECIA®) is currently approved for treatment BPH and male pattern hair loss. The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than either drug alone. The Company anticipates submitting an NDA for its TADFIN™ tablet under the 505(b)(2) regulatory pathway in the second half of calendar year 2019. Veru is also developing Tamsulosin DRS granules and Tamsulosin XR capsules which are formulations of tamsulosin, the active ingredient in FLOMAX®, which Veru has designed to avoid the "food effect" inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance (NDA submission expected in 2019).

Veru's commercial products include the FC2 Female Condom / FC2 Internal Condom® (FC2), an FDA-approved product for the dual prevention of unwanted pregnancy and sexually transmitted infections, and the PREBOOST® medicated individual wipe for the prevention of premature ejaculation. Veru's Female Health Company Division markets the FC2 commercially and in the public health sector both in the U.S. and globally. FC2 is available by prescription in the U.S. including through the virtual doctor smartphone app "HeyDoctor" at www.fc2.us.com. For PREBOOST® Veru has a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, and the Company has also entered into a multi-year exclusive supply and distribution agreement with Roman Health Ventures, Inc., a premier and fast-growing men's health and telemedicine company that discreetly sells men's health products via the internet. To learn more about these products please visit www.verupharma.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:
The statements in this release that are not historical facts are "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this release include statements relating to the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies, clinical study results and FDA submissions and the market potential for the Company's drug candidates. Any forward-looking statements in this release are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions, and if any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; product demand and market acceptance; competition in the Company's markets and the risk of new or existing competitors with greater resources and capabilities and new competitive product introductions; price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed

payments; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; the Company's reliance on its international partners and on the level of spending by country governments, global donors and other public health organizations in the global public sector; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; the Company's production capacity, efficiency and supply constraints and interruptions, including due to labor unrest or strikes; risks related to the costs and other effects of litigation, including product liability claims; the Company's ability to identify, successfully negotiate and complete suitable acquisitions or other strategic initiatives; the Company's ability to successfully integrate acquired businesses, technologies or products; and other risks detailed in the Company's press releases, shareholder communications and Securities and Exchange Commission filings, including the Company's Form 10-K for the year ended September 30, 2018. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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