Veru Announces Acceptance of Four Abstracts for Presentation at the Genitourinary Cancer Symposium in February 2019

MIAMI, Jan. 15, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, today announced that four abstracts have been accepted for poster presentation at the upcoming 2019 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium to be held February 14-16, 2019, at the Moscone West Building in San Francisco, California.

Three of the presentations will be for VERU-111, the Company's proprietary, next generation, first-in-class selective oral tubulin inhibitor for the treatment of advanced prostate cancer which is enrolling in a Phase1b/2 clinical study, and the fourth presentation will be for zuclomiphene citrate (VERU-944), a proprietary oral estrogen receptor agonist drug for the treatment of hot flashes caused by androgen deprivation therapy (ADT) for men with advanced prostate cancer which is currently enrolling in a Phase 2 clinical trial.

Additional information on the meeting can be found on the ASCO Genitourinary Cancers Symposium website: https://gucasym.org/. The full abstracts will be made available online via https://meetinglibrary.asco.org at 5:00 PM (EST) on February 11, 2019.

Presentation details:

- Abstract 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
  Abstract Number: TPS330
  Board Number: N6
  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

- Abstract Title: VERU-111, a novel oral inhibitor of α and β 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
  Abstract Number: 167
  Board Number: G10
  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

- Abstract Title: The oral α and β 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
  Abstract Number: 299
  Board Number: D7
  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

- Abstract 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
  Abstract Number: TPS338
  Board Number: N14
  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

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 urology 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 expects to enroll the first patient in the VERU-111 Phase 1b/2 clinical trial in January 2019.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology. Tamsulosin DRS granules and Tamsulosin XR capsules are formulations of tamsulosin, the active ingredient in FLOMAX®, which Veru has developed 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 is also developing Tadalafil/Finasteride combination tablet. 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*(NDA submission expected in 2019).

Veru’s Female Health Company Division markets the FC2 Female Condom / FC2 Internal Condom®, 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. The FC2 Female Condom / FC2 Internal Condom is marketed 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. FC2 improves the lives, health and well-being of women around the world. For PREBOOST® Veru has a co-promotion and distribution agreement with Timm Medical Technologies, Inc., a specialty urology sales organization, and the Company also recently entered into a US distributor agreement with 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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