Veru Initiates Clinical Trial for Proprietary, Novel, First-in-Class Drug for Advanced Prostate Cancer

–Open-Label Phase 1b/2 Clinical Trial Results Expected by Year-End– — Drug Addresses Significant Unmet Medical Need —

MIAMI, Jan. 22, 2019 (GLOBE NEWSWIRE) — Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, today announced that it has initiated and enrolled the first patient in a clinical trial of its proprietary, next generation prostate cancer drug, VERU-111. The open-label Phase 1b/2 clinical trial for VERU-111, a novel oral drug, will be evaluated in men with metastatic refractory prostate cancer that would be given prior to intravenous chemotherapy.

“Upon successful completion of this important clinical trial, we will move forward with additional clinical studies including a pivotal Phase 3 trial,” commented Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Based on earlier preclinical studies, VERU-111 should be effective against refractory prostate cancer and have a more favorable safety profile compared to intravenous taxanes. Drugs for advanced prostate cancer currently have over $3 billion in U.S. annual sales. Our preclinical studies also suggest that VERU-111 may be effective as a treatment for breast, ovarian, pancreatic and other prevalent cancers.”

“The study will be conducted in approximately five centers in the United States, with results expected by the year-end of calendar 2019. In Phase 1b, the dose escalation portion of the study, patients will receive VERU-111 to determine the optimal dose for testing in Phase 2. In Phase 2, VERU-111 will be assessed for the drug’s effectiveness in lowering prostate-specific antigen blood levels, the primary endpoint.”

Dr. Mark Markowski, MD, PhD, Assistant Professor of Oncology, The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, stated: “VERU-111 addresses a large and growing medical need. New therapies are needed for men with metastatic castration resistant prostate cancer who have also become resistant to androgen blocking agents. Having a drug like VERU-111, a novel, oral selective alpha and beta tubulin inhibitor, would be a valuable option for these men that otherwise have to be treated by intravenous taxane chemotherapy.”

Dr. Mario Eisenberger, MD, Dale Hughes Professor of Oncology, The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center and a member of Veru’s Board of Directors, stated: “While major therapeutic advances have been accomplished with androgen receptor (AR) targeting drugs, it is clear that further improvements in the outcomes of prostate cancer patients rely on drugs and modalities that exert their anti-tumor effects through different mechanisms. VERU-111 has shown significant biological activity against a variety of in vitro and in vivo prostate cancer tumor cells resistant to AR targeting drugs at a level much superior to current FDA approved taxanes. Preclinical toxicology studies suggest that the tolerability of orally administered VERU-111 is superior to the widely used taxanes, docetaxel and cabazitaxel, especially in terms of hematological toxicities.”

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 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 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 (Tad-Fin Combination 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 Tad-Fin Combination 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 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, the market potential for the Company's drug candidates, and whether clinical trial results support the effectiveness and safety profile shown by preclinical studies for VERU-111. 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.

Contact:
Kevin Gilbert 786-322-221
