October 2, 2019

Veru Announces Full Enrollment of Phase 2 Trial in Men with Prostate Cancer Treatment Induced Hot Flashes

-- Potential to be First FDA-Approved Drug for ADT induced Hot Flashes–

-- Topline Clinical Data Anticipated Fall 2019 --

MIAMI, Oct. 02, 2019 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), The Prostate Cancer Company, an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and supportive care, today announced that it has achieved full enrollment for its Phase 2 clinical study of zuclomiphene citrate, a nonsteroidal oral estrogen receptor agonist for the treatment of androgen deprivation hormone therapy (ADT) induced hot flashes in men who have advanced prostate cancer.

“Our proprietary zuclomiphene citrate product has the potential to be the first FDA-approved treatment for this most common and debilitating side effect of ADT as hot flashes occur in up to 80% of men,”* said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Hot flashes induced by ADT can be so severe as to cause delay or early discontinuation of ADT.”

The Phase 2 clinical study is a double-blind randomized placebo-controlled dose finding study evaluating two doses of oral daily zuclomiphene (10mg or 50mg) treatment versus placebo in approximately 95 men with advanced prostate cancer who have ADT induced moderate to severe hot flashes. The clinical study has a treatment duration of 12 weeks and is being conducted in 24 clinical centers in the United States. The primary endpoint is the frequency of moderate to severe hot flashes. Secondary endpoints include severity of hot flashes and improvement in bone markers.

“We are very pleased to have achieved this important enrollment milestone. We look forward to seeing the topline efficacy results and safety data from this Phase 2 trial in the Fall of 2019,” said Dr. Steiner. "We remain on track for initiation of the Phase 3 clinical study in early 2020. Based on Independent market research sponsored by the Company, US peak sales for zuclomiphene citrate are estimated to be approximately $600 million per year.”

About Hot Flashes in Men with Prostate Cancer Undergoing Hormonal Therapy
ADT is widely used to treat men with advanced prostate cancer. Approximately 600,000 men in the US are currently on ADT, which includes but is not limited to, Lupron®, Eligard® and Firmagon®. The symptom of hot flashes is the most common side effect of ADT. These

hot flashes can range from bothersome to debilitating. Associated symptoms may include anxiety and palpitations. Hot flashes usually last from a few seconds to several minutes but can persist for up to 20 minutes. Unlike postmenopausal hot flashes, ADT induced hot flashes in many patients do not get better or resolve over time.

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and prostate cancer supportive care as well as urology specialty pharmaceuticals. The Veru prostate cancer pipeline includes VERU-111, zuclomiphene citrate and VERU-100. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in an open label Phase 1b/2 clinical trial. Zuclomiphene citrate is an oral 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-100 is a novel, proprietary peptide formulation for androgen deprivation therapy (ADT) with multiple beneficial clinical attributes addressing the shortfalls of current FDA approved ADT formulations for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration --- a problem which occurs with currently approved LHRH agonists. Currently, there are no GnRH antagonists commercially approved beyond 1 month. VERU-100 is anticipated to enter a Phase 2 dose finding study in early 2020.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFIN®) for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful preNDA meeting with FDA and the expected submission of the NDA for TADFIN is summer of 2020. 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.

The Company's commercial products include the FC2 Female Condom / FC2 Internal Condom® ("FC2"), an FDA-approved product for the dual protection of unwanted pregnancy and sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the prevention of premature ejaculation (also marketed as Roman Swipes). The Company’s Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. FC2 is available by prescription and OTC in the U.S. at www.fc2.us.com. In the global public health sector,

the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. For our premature ejaculation product, marketed as “Roman Swipes”, the Company has entered into a U.S. distributor 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 website www.getroman.com. To learn more about Veru products please visit www.verupharma.com.

* 1 Gomella LG et al BJU Int S1:25-29 2007; Karling P et al. J Urol 152:1170-1173 1994; Gonzalez BD et al J Urol 194:690-695 2015|

"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 regarding the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, clinical study results including potential benefits 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. 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 therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or 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; the risk that delays in orders or shipments under government tenders could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; 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 potential disruption of production at the Company's manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's facilities, product testing, transportation delays or regulatory actions; 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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