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Veru Announces Positive Top-Line Interim Data from Phase 2 Clinical Trial of Zuclomiphene to Treat Hot Flashes in Men with Prostate Cancer on Androgen Deprivation Therapy

-- Plans to Advance Zuclomiphene into Pivotal Phase 3 Clinical Trial in First Half of 2020 --

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

MIAMI, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), The Prostate Cancer Company, an oncology and urology biopharmaceutical company developing novel medicines for the management of prostate cancer, today announced positive top line data interim results from 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, also known as vasomotor symptoms, in men who have advanced prostate cancer.

The Phase 2 clinical study is a double-blind randomized placebo-controlled dose finding study evaluating daily oral doses of Zuclomiphene (10mg versus 50mg) in 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. A topline interim analysis was performed in which 93 men with ADT-induced hot flashes were enrolled. The objectives of the study were to evaluate the estrogenic activity of Zuclomiphene on hot flashes, to confirm a no-effect dose (the 10mg dose), and to evaluate the effect of a higher dose (the 50mg dose) of Zuclomiphene on the frequency of moderate to severe hot flashes at Day 42.

The topline interim clinical results demonstrate that a statistically significant decrease in moderate to severe hot flashes from baseline was observed in the 50mg treatment group ($p<0.001$). The 10mg treatment group, as expected, did not show a statistically significant reduction in hot flashes from baseline ($p=0.15$). Based on this result, the 10mg dose group is established as a no-effect dose as was planned for in the study. Furthermore, when comparing the 50mg treatment group (-41% reduction in hot flashes from baseline) versus the 10mg treatment group (-21% reduction in hot flashes from baseline), a statistically significant reduction ($p=0.03$) in the frequency of moderate to severe hot flashes at Day 42 is

observed. Moreover, the observed estrogenic activity of the 50mg group was statistically different from 10mg and placebo groups ($p<0.0001$).

Zuclomiphene appears to be well tolerated as there have been no reports of drug related serious adverse events nor drug related severe adverse events and no observations of adverse events of special interest, such as breast enlargement or pain, or venothromboembolic events (blood clots in legs or lungs, or stroke) in the safety database for the Phase 2 clinical study. Adverse events of special interest are side effects commonly seen with off label use of steroidal estrogens and progestins for hot flashes.

The 50mg treatment group shows statistical and clinically meaningful reductions in moderate to severe hot flashes from baseline without any clinically relevant safety findings. The Company plans to meet with FDA for an End of Phase 2 meeting and following this discussion with FDA, advance Zuclomiphene into a pivotal Phase 3 clinical trial for the treatment of ADT-induced moderate to severe hot flashes in men with prostate cancer in the first half of 2020.

“This is an exciting time for Veru. These Phase 2 clinical interim results have established that Zuclomiphene has clinically meaningful estrogen activity against moderate to severe hot flashes with a good safety profile allowing us to advance to a pivotal Phase 3 clinical trial of Zuclomiphene,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Without the side effects seen with steroidal estrogens or progestins, we believe that Zuclomiphene has the potential to be the first FDA approved therapy for ADT-induced hot flashes to address this area of significant unmet medical need. Furthermore, an independent market analysis sponsored by the Company confirmed the large market opportunity as Zuclomiphene annual sales could be between $600-800 million in the US alone.”

“Our plan is to have an end of Phase 2 meeting with FDA in early 2020 and to initiate a Phase 3 clinical development in first half of 2020. We are pleased with the significant clinical progress we are making in advancing our entire product development program. With each milestone achievement, we move inexorably closer to our goal of providing prostate cancer patients with multiple continuum of care therapies and supportive care medicines,” added Dr. Steiner.

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. Symptoms that may accompany these hot flashes include anxiety and palpitations, cognitive impairment and disturbed sleep. 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 Zuclomiphene Citrate
Zuclomiphene citrate is a novel, proprietary, oral, nonsteroidal, estrogen receptor agonist. Today the Company announced that a Phase 2 clinical trial of Zuclomiphene citrate demonstrated a statistically significant reduction in the frequency of moderate to severe hot

flashes in men with advanced prostate cancer on ADT therapy. The Company plans to initiate a Phase 3 clinical trial in the first half of calendar year 2020. Based on an independent market analysis sponsored by the Company, expected U.S. sales potential for Zuclomiphene citrate is estimated to be between $600-800 million annually.

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for the management of prostate cancer. The Veru prostate cancer pipeline includes VERU-111, Zuclomiphene citrate and VERU-100. VERU-111 is an oral, next-generation, first-in-class 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. The clinical development program for VERU-111 is being expanded with plans to initiate three additional Phase 2 studies: metastatic pancreatic cancer, metastatic breast cancer and postchemotherapy (taxane) metastatic castration resistant prostate cancer. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being evaluated for estrogenic activity in a Phase 2 trial (Stage 1 testing placebo, Zuclomiphene 10mg, and Zuclomiphene 50mg) to treat hot flashes, a common side effect caused by androgen deprivation therapy (ADT) in men with advanced prostate cancer. Veru plans to initiate a Phase 3 clinical trial for Zuclomiphene in the first half of 2020. VERU-100 is a novel, proprietary peptide formulation for ADT with multiple potential beneficial clinical attributes addressing the shortfalls of current FDA-approved ADT formulations for the treatment of 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 luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonists commercially approved beyond a one-month injection. 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 of 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 pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN is the second half of calendar year 2020. Veru is also developing Tamsulosin XR capsules which is a formulation 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 against unwanted

pregnancy and the transmission of sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. 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. In the U.S., FC2 is available by prescription through the Company's multiple telemedicine and internet pharmacy partners, retail pharmacies, as well as OTC via the Company's website 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. PREBOOST® is marketed exclusively through online sales in the U.S. under the Roman Swipes brand name by Roman Health Ventures Inc. Roman is a leading telemedicine company that discreetly sells men's health products via the internet website www.getroman.com. To learn more about Veru products please visitwww.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 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 absence of adverse events 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; clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; 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, 2019. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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