January 21, 2020

# Veru Announces Acceptance of Two Abstracts for Presentation at the Genitourinary Cancer Symposium in February 2020

MIAMI , Jan. 21, 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 that two of its abstracts have been accepted for presentation at the upcoming 2020 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium to be held February 13-15, 2020, at the Moscone West Building in San Francisco, California.

One of the presentations will provide preclinical data on VERU-100, the Company's novel, proprietary peptide formulation for androgen deprivation therapy (ADT) developed with multiple potential beneficial clinical attributes to address 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.

The other presentation reports findings from a recent study in a contemporary cohort of men on ADT to determine the magnitude of the impact that hot flashes are having on these men and their disease management. The Company has a novel, proprietary, oral, nonsteroidal, estrogen receptor agonist, Zuclomiphene citrate, that is currently being evaluated in a Phase 2 clinical study to treat hot flashes, one of the most common and impactful side effects caused by ADT.

Additional information on the meeting can be found on the ASCO Genitourinary Cancers Symposium website: http://gucasym.org/. The full abstracts will be made available online via https://meetinglibrary.asco.org at 5:00 PM (EST) on February 10, 2020.

Presentation details:

1. **Abstract Title:** Determination of the ability of a novel, long-acting subcutaneous GnRH antagonist, VERU-100, to castrate without a testosterone surge in a rat model
   **Presenter:** Robert H. Getzenberg, Ph.D.
   **Abstract Number:** 128
   **Board Number:** F8

**Session Information:** Poster Session A: Prostate Cancer
**Date/Time:** 02/13/2020, 11:30 AM – 1:00 PM and 5:30 PM – 6:30 PM

2. **Abstract Title:** Survey of ADT-induced estrogen deficiency-related side effects in a contemporary cohort of men with advanced prostate cancer
**Presenter:** Robert H. Getzenberg, Ph.D.
**Abstract Number:** 235
**Board Number:** B13
**Session Information:** Poster Session B: Prostate Cancer; Urothelial Carcinoma; Penile, Urethral, Testicular, and Adrenal Cancers
**Date/Time:** 02/14/2020, 12:15 PM -1:45 PM; 5:15 PM – 6:15 PM

**About VERU-100**
VERU-100 is a long-acting 3-month subcutaneous depot GnRH antagonist for the treatment of hormone sensitive advanced prostate cancer. Currently, there are no GnRH antagonists commercially approved beyond 1 month, which would make VERU-100, if approved, the only commercially available GnRH antagonist 3-month depot. Based on regulatory clarity obtained in the pre-IND meeting with the FDA in May 2019, the Company plans to submit the IND application for VERU-100 in early 2020. Androgen deprivation therapy for advanced prostate cancer is an established multi-billion-dollar global market.

**About Zuclomiphene Citrate**
Zuclomiphene citrate is a novel, proprietary, oral, nonsteroidal, estrogen receptor agonist being evaluated as a treatment for hot flashes caused by androgen deprivation therapy for men with advanced prostate cancer. Hot flashes, also known as vasomotor symptoms, are one of the main reasons why men want to stop androgen deprivation therapy. Recently the Company announced positive top-line interim data from a Phase 2 clinical trial of Zuclomiphene citrate which demonstrated a statistically significant reduction in the frequency of moderate to severe hot flashes in men with advanced prostate cancer on ADT therapy. There have been no reports of gynecomastia, breast pain, or venothromboembolic events (blood clots in legs or lungs, or stroke) in the Intent to Treat safety database in the Phase 2 clinical study which are side effects commonly seen with off label use of steroidal estrogens and progestins for hot flashes in these kinds of patients. 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; the risk that the Company's products may not be commercially successful; 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; the risk that the Company's will be affected by regulatory developments, including a reclassification of products*; *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 or the Company's U.S. prescription business 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, including the Company's South Africa female condom 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 and/or the timing of*

*orders could be delayed; penalties and/or debarment for failure to satisfy tender awards;the Company's recent South Africa female condom tender award could be subject in the future to reallocation for potential local manufacturing initiatives, which could reduce the size of the award to the Company; 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 Annual Report on 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](www.verupharma.com/investors).*

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Source: Veru Inc.