December 3, 2018

Veru Announces First Patient Dosed in Bioequivalence Clinical Trial for Combination Tadalafil – Finasteride Tablet for Benign Prostatic Hyperplasia

-- Combination Tablet Treats BPH Symptoms; Shrinks Prostate and Prevents BPH Progression --

-- NDA Submission Target Mid 2019 --

MIAMI, Dec. 03, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, announced today that the Company has dosed its first patient for its bioequivalence study of Tadalafil (Cialis®) and Finasteride (PROSCAR®) combination tablet for benign prostatic hyperplasia (BPH) (Tad-Fin Combination Tablet). Tad-Fin Combination Tablet is designed for the co-administration of tadalafil and finasteride to improve patient compliance and convenience for men suffering from BPH. Finasteride shrinks the prostate while tadalafil treats the symptoms of BPH.

The bioequivalence study will enroll 36 patients and will be completed in approximately four weeks. Clinical results will be reported in the first calendar quarter of 2019. In addition, the Company has initiated manufacturing of the commercial grade product through its contract manufacturer to be used for an NDA submission to the U.S. Food and Drug Administration (FDA). If successful, NDA submission target is mid-2019.

“The co-administration of tadalafil and finasteride has been clinically proven to significantly improve lower urinary tract symptoms in men with BPH and an enlarged prostate, all with attendant benefits for erectile dysfunction,” commented Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru.* “Co-administration reduces the risk of acute urinary retention and the potential need for surgery while shrinking prostate size. We believe our Tad-Fin Combination Tablet will provide convenience which should substantially increase compliance improving the health of patients.”

About Tadalafil/Finasteride Combination Tablet
Tad-Fin Combination Tablet is a new combination tablet containing 5 mg tadalafil and 5 mg finasteride to improve lower urinary tract symptoms in men with BPH and an enlarged prostate. Finasteride inhibits the enzyme 5-alpha-reductase, which converts testosterone to the more potent dihydrotestoserone. By doing so, it can act to shrink the prostate, prevent the progression of BPH, reduce the risk of acute urinary retention and reduce the potential

need for surgery. Tadalafil is a PDE5 inhibitor that has efficacy in relieving the symptoms of BPH by relaxing the smooth muscle of the prostate and is also indicated for erectile dysfunction. Co-administration of tadalafil and finasteride is currently FDA approved for the initial treatment of symptoms of BPH for up to 26 weeks.

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer and prostate cancer supportive care as well as near term specialty pharmaceuticals to address significant unmet needs in urology.

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 small molecule that targets and binds to 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 VERU-111 to enter a Phase 1b/2 clinical trial in late 2018.

Veru is also advancing four 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 tablets for inhibition of both phosphodiesterase type 5 (PDE5) and 5-alpha-reductase to shrink an enlarged prostate, to treat symptoms of BPH and to treat erectile dysfunction (NDA submission expected in 2019). Finally, Veru is developing Solifenacin DRG granules, a formulation of a selective M3 muscarinic receptor antagonist for the treatment of overactive bladder in patients who have difficulty with swallowing tablets (NDA submission expected in 2019).

Veru’s currently marketed products are the PREBOOST® medicated individual wipe for the prevention of premature ejaculation and the FC2 Female Condom®. The Female Health Company Division markets the FC2 Female Condom® in the global public health sector to improve the lives, health and well-being of women around the world. To learn more please visit www.verupharma.com.

*Casabé A et al. Journal of Urology 191:727-733 2014

"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 and the anticipated timeframe for clinical studies, clinical study results and FDA submissions. 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, 2017. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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Source: Veru Inc.