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First Patient Enrolled in Phase 2 Study of Zuclomiphene Citrate for Treatment of Hot Flashes Caused by Androgen Deprivation Therapy

MIAMI, Oct. 01, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, today announced the enrollment of the first patient in its Phase 2 study of zuclomiphene citrate for the treatment of hot flashes caused by androgen deprivation therapy (ADT) for men with advanced prostate cancer. The double-blind, placebo-controlled, dose-finding study is designed to evaluate the safety and efficacy of daily oral zuclomiphene citrate in patients with moderate to severe hot flashes caused by ADT for advanced prostate cancer. The study, conducted at multiple U.S. sites, is designed to enroll approximately 120 patients randomized to one of four treatment arms (zuclomiphene 10 mg, 50 mg, 100 mg, or placebo). The primary endpoint of the study is the mean change in frequency and severity of hot flashes relative to baseline at week 4.

“Up to 80% of all patients receiving androgen deprivation therapy experience hot flashes and 30% to 40% experience moderate to severe hot flashes that can be debilitating,” commented Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru.

“Unfortunately, hot flashes can be a reason why men decide to not start or to stop receiving ADT which is an effective prostate cancer therapy. Given the large prostate cancer patient population on ADT and the fact that there are no current FDA-approved therapies for this indication, we see significant potential for zuclomiphene to impact prostate cancer care. Our proprietary zuclomiphene small molecule compound has an established mechanism of action and a long history of relevant clinical safety information, which are key advantages for clinical development. We are pleased to have reached the stage of first patient enrolled and look forward to reporting top-line results in the first half of 2019.”

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, agent that targets alpha and beta subunits caused by cells to

form cellular microtubules to treat castration and novel androgen blocking agent (abiraterone or enzalutamide) resistant metastatic prostate cancer that Veru expects to enter Phase 1/2 development 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, a super selective alpha-1 adrenergic receptor antagonist for the treatment of benign prostatic hyperplasia (BPH), that avoid the “food effect” 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, 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.

"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 and the market potential for zuclophene. 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.