November 13, 2018

Veru Advances Novel, First-in-Class Oral Tubulin Inhibitor for Refractory Metastatic Prostate Cancer

-- Submits Investigational New Drug Application to FDA --

-- Open Label Phase 1b/2 Clinical Trial Expected to Begin before end of 2018 --

MIAMI, Nov. 13, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company, today announced that it has submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for VERU-111 (bisindole), a first-in-class, next generation, proprietary, oral tubulin inhibitor for the treatment of refractory metastatic prostate cancer. The Company plans to conduct an open label Phase 1b/2 clinical trial in men with metastatic castration resistant prostate cancer that have also become resistant to, or who have failed to respond to, abiraterone or enzalutamide.

“Submission of this IND is an important milestone in advancing into humans VERU-111 -- a first-in-class, next generation, proprietary, oral tubulin inhibitor. VERU-111 is being developed for men who have metastatic castration resistant prostate cancer that have also become refractory to, or who have failed to respond to, abiraterone or enzalutamide. This group of men may be the largest growing segment of advanced prostate cancer unmet need. These men with refractory prostate cancer are now being offered intravenous administration of anti-tubulin taxanes that can have significant safety limitations like hypersensitivity, myelosuppression (neutropenia) and neurotoxicity,” commented Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru.

“Based on our extensive preclinical experience, we believe VERU-111 should demonstrate significant antitumor activity against metastatic castration and novel androgen blocking agent (enzalutamide or abiraterone) resistant prostate cancers with oral dosing and a favorable safety profile. We expect to begin an open label Phase 1b/2 clinical trial before the end of 2018. The open label design of the trial means that we will have safety and efficacy data as early as the first half of calendar year 2019.”

About VERU-111

VERU-111 is a novel, next generation oral anti-tubulin therapy that targets alpha and beta tubulin subunits. In animal models, VERU-111 delivered by oral administration demonstrated significant anti-tumor activity in models of metastatic, castration and novel androgen blocking agent (abiraterone or enzalutamide) resistant prostate cancer. In the preclinical

toxicology studies, VERU-111, at oral doses that had significant antitumor effects, did not result in neutropenia or myelosuppression, common dose limiting side effects of other antitubulins including intravenous taxanes or intravenous vinca alkaloids. Also, VERU-111 had antitumor effects in other cancer types including preclinical human models for triple negative breast cancer, ovarian cancer and pancreatic cancer.

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 1b/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 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.