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Veru Announces Publication of Data from Three Cancer Studies as Part of the Upcoming American Society of Clinical Oncology Annual Meeting

--Data of Company's Proprietary Drug, Oral VERU-111, Shows Efficacy in Multiple Cancer Models: Human Taxane-Resistant Triple Negative Breast Cancer, Pancreatic Cancer and Ovarian Cancer--

MIAMI, May 17, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ:VERU), a urology and oncology biopharmaceutical company, today announced the publication of data from preclinical studies of VERU-111, a novel oral alpha and beta tubulin inhibitor, that showed efficacy in chemotherapy resistant tumor types. Specifically, VERU-111 reduced tumor growth in a paclitaxel sensitive and resistant triple negative breast cancer (TNBC) model, as well as ovarian cancer and pancreatic cancer models. Three abstracts, which include data related to each of the three cancers, were published as part of the upcoming 2018 American Society of Clinical Oncology Annual Meeting in Chicago.

Triple negative breast cancer is highly aggressive and has poor prognosis due to the frequent development of drug resistance. The study being published evaluated oral administration of VERU-111 compared with IV docetaxel in a paclitaxel resistant TNBC model. IV docetaxel had little impact on tumor growth whereas oral VERU-111 resulted in almost complete inhibition of TNBC tumor growth at 12.5 mg/kg, as well as significantly reduced tumor metastasis.

Metastatic ovarian cancer is a highly lethal gynecological malignancy. Although many patients with ovarian cancer initially respond to treatment with taxane therapies, resistance is common. The study being published evaluated oral administration of VERU-111 in an orthotopic ovarian cancer model. Orally administered VERU-111 had a significant (86%) reduction in ovarian tumor growth and the animals receiving oral VERU-111 had no identifiable liver or spleen metastases.

Likewise, the prognosis for pancreatic cancer is poor since pancreatic cancer usually does not cause recognizable symptoms in its early stages and the disease is typically not diagnosed until it has spread beyond the pancreas itself. The study being published evaluated oral administration of VERU-111 compared with paclitaxel, vinorelbine and colchicine in a pancreatic cancer model. Orally administered VERU-111 had significant impact on pancreatic tumor growth and mechanistically arrested the cell cycle and induced

apoptotic pathways in this model.

“We believe that VERU-111 has the potential to become an important therapeutic option for ovarian, pancreatic and breast cancer patients, as well as with many other common cancer types. We are currently performing the required toxicity studies and are planning our IND submission and first clinical studies for later this year,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru.

About VERU-111

VERU-111 is a novel oral therapy targeting alpha and beta tubulin for the treatment of metastatic prostate, breast, endometrial, ovarian, and other cancers. In 2017, there were approximately 161,000 new cases of prostate cancer in the U.S. and about 25% of these men will die from the disease. In the U.S., 5% of men with prostate cancer will have metastatic cancer and up to 30% of men with high-risk, localized prostate cancer will develop metastatic cancer following initial therapy. The median survival of patients with metastatic prostate cancer ranges from 3.2 to 4.5 years. For these men, the 1st line therapy is androgen deprivation therapy, or medical castration. Although most will initially respond, nearly all these patients will progress to metastatic castration resistant prostate and have a poor prognosis with an average survival of 1.5 years. New 2nd line hormonal agents, like XTANDI® (enzalutamide) and ZYTIGA® (abiraterone/prednisone) have resulted in an additional four to five months of average survival, but nearly all men on these agents will develop progressive metastatic prostate cancer.

Drugs like VERU-111 that target tubulin, the subunits of microtubules, have been shown to be the most effective targeted cytotoxic chemotherapy for the treatment of metastatic prostate cancer. Microtubules are critical for cancer cell replication to stimulate genes for cancer cell proliferation. Docetaxel and cabazitaxel are examples of FDA-approved chemotherapy drugs that are given intravenously (IV) that target tubulin to treat metastatic prostate cancer. Although effective, the challenges for this class of chemotherapy drugs, also known as taxanes, include that they must be given intravenously (IV) and that the cancer cells develop resistance to taxanes. There are also serious safety concerns with IV taxanes which include serious hypersensitivity reactions, myelosuppression and neurotoxicity such as peripheral neuropathy and muscle weakness.

Unlike taxanes which bind to just the beta subunit of tubulin, VERU-111 binds strongly to both the alpha and beta subunits of tubulin. VERU-111 has: high oral bioavailability; less resistance as it does not interact with multiple drug resistance proteins so it cannot be pumped out of the cancer cell; minimal drug to drug interactions and high activity against many tumor types including: prostate cancer resistant to drugs like enzalutamide, AR-V7 positive and taxanes, as well as triple negative breast cancer, ovarian cancer, pancreatic cancer, lung cancer, and melanoma. In preclinical studies, VERU-111 appears to have less toxicity and less suppression of white blood cells compared to taxanes and other chemotherapy agents.

Production of the VERU-111 active pharmaceutical ingredient and preclinical safety toxicology studies required for an IND are expected to be completed in 2018. We anticipate filing an IND in 2018 and Phase 1/2 studies are planned for late 2018. Phase 1 studies of VERU-111 are planned in men who have metastatic prostate cancer that has progressed while taking androgen deprivation therapy and abiraterone or enzalutamide as well as in

patients with metastatic breast, endometrial, and ovarian cancers. In the U.S., there is a $5 billion annual market for 2nd line hormone therapies for prostate cancer and a $4.8 billion annual market for IV-given taxanes and vinca alkaloids chemotherapies (docetaxel $1 billion and cabazitaxel $500 million in prostate cancer) per Decision Resources Group and Allied Market Research. Second line hormonal therapies like enzalutamide and abiraterone/prednisone have almost complete cross-resistance and should not be used in sequence for the treatment of metastatic prostate cancer. VERU-111 could be substituted for IV given docetaxel and cabazitaxel antitubulin chemotherapies. VERU-111 could also be developed as an oral dosing alternative to chemotherapies for the treatment of metastatic breast, endometrial and ovarian cancers as these tumors that responded to IV taxane chemotherapies.

About Veru Inc.
Veru Inc. (Veru) is a urology and oncology biopharmaceutical company. The company is currently developing drug product candidates: Tamsulosin DRS, slow release granules, and Tamsulosin XR capsules for lower urinary tract symptoms of benign prostatic hyperplasia (BPH) (NDA planned 2018), Solifenacin DRG, slow release granules, for overactive bladder (urge incontinence, urgency and frequency of urination) (NDA planned 2019), Tadalafil/finasteride combination capsule for restricted urination because of an enlarged prostate (NDA planned 2019), VERU-944 (cis-clomiphene citrate) for hot flashes in men associated with prostate cancer hormone treatment (planned Phase 2 in 2018), and VERU-111 a novel oral anti-tubulin cancer therapy targeting alpha & beta tubulin for a variety of malignancies, including metastatic prostate, breast, endometrial and ovarian cancers (planned Phase 1/2 in 2018).

To help support these clinical development programs, the company markets and sells the PREBOOST® medicated individual wipe, which is a male genital desensitizing drug product for the prevention of premature ejaculation which is being co-promoted with Timm Medical Technologies, Inc. and the FC2 Female Condom® (now available by prescription in the US including through the virtual doctor smartphone app “HeyDoctor” at www.fc2.us.com) in the United States and through The Female Health Company Division in the Global Public Health Sector. The Female Health Company Division markets 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. More information about Veru and its products can be found at www.verupharma.com, www.PREBOOST.com, www.fc2.us.com and www.fc2femalecondom.com. For corporate and investor-related information about the Company, please visit https://verupharma.com/investors.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:
The statements in this release that are not historical fact 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 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 the extensive governmental regulation, and effects of healthcare insurance and regulation, including reductions in reimbursement and coverage or reclassification of the 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; 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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