March 16, 2018

Veru Announces Presentation of Data Demonstrating Efficacy of VERU-111 in a Taxane Resistant Human Prostate Cancer Model at the 2018 Annual EAU Congress

MIAMI, March 16, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ:VERU), a biopharmaceutical company focused on urology and oncology, announced that data from a preclinical study of VERU-111, a novel oral alpha and beta tubulin inhibitor, showing potent activity against paclitaxel sensitive and resistant prostate cancer models, will be presented in a session at the 2018 European Association of Urology (EAU) 33rd Annual Congress to be held March 16-20, 2018, at the Bella Center in Copenhagen, Denmark.

Chemotherapy prolongs survival and improves the quality of life of patients with metastatic hormone sensitive and castration resistant prostate cancer. Despite this, many men are not responsive or quickly become resistant to these drugs and these drugs must be given through intravenous (IV) infusion with significant side effects. The Veru study being presented evaluated oral administration of the novel oral alpha and beta tubulin inhibitor, VERU-111, compared with IV docetaxel in a resistant prostate cancer model. IV docetaxel had no impact on tumor growth whereas oral VERU-111 resulted in almost complete inhibition of tumor growth at 10 mg/kg (3 days/week) as well as 20 mg/kg (1 day/week). In early toxicity studies, VERU-111 has been well tolerated and the animals have gained weight during treatment.

“This exciting data and the unique properties of VERU-111 provide further support for the utility of this drug to fill the important clinical unmet need in prostate cancer of having oral administration, as well as lack of drug resistance, myelosuppression and hypersensitivity reactions. Further, this drug has been shown to have preclinical activity in other cancer types and should have clinical activity in these other cancers as well,” said James Dalton, Ph.D., Dean of the College of Pharmacy and Professor of Pharmaceutical Sciences at the University of Michigan and co-author of the presentation.

Details on the presentation are as follows:

Title: VERU-111, a novel oral α and β tubulin inhibitor, has potent activity against paclitaxel sensitive and resistant prostate cancer.

Presenter: Robert H Getzenberg, PhD

Session Date and Time: Saturday, March 17, 2018 at 15:00-17:30

Location: Red Area, Room 3

About VERU-111
VERU-111 is a novel oral therapy targeting alpha and beta tubulin for the treatment of metastatic prostate, breast, pancreas, melanoma, 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. For men who have developed metastatic prostate cancer, 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.

VERU-111 targets tubulin, the subunits of microtubules, that have been shown to be the most effective targeted cytotoxic chemotherapy for the treatment of hormone resistant 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 also planned for later this year. 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, ovarian cancers along with other cancer types as these tumors have responded to taxane chemotherapies.

About Veru Inc.
Veru Inc. (Veru) is a biopharmaceutical company focused on urology and oncology. 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 tablet 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, the anticipated timeframe for clinical studies and FDA submissions, future demand for FC2 and potential orders of FC2 by public sector customers. Any forward-looking statements in this 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 inherently subject to known and unknown risks and uncertainties. The Company's actual results and future developments could differ materially from the results or developments expressed in, or implied by, these forward-looking statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; the expected timing of the clinical studies and regulatory approval of products under development; the outcome of the clinical

trials and drug studies and that such outcomes will support marketing approval and commercialization; risks relating to the ability of the Company to obtain sufficient financing or raising capital on acceptable terms when needed to fund development and Company 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 from the extensive governmental regulation, effects of healthcare insurance and regulation, including reductions in reimbursement and coverage. 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 covering the products and processes and in successfully enforcing them against third parties; expectations regarding patent coverages; the possibility of infringing a third party's patents or other intellectual property rights; 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, or 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; 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; 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 Company's Annual Report on 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.