February 6, 2018

Veru Announces Presentation of Data Demonstrating Efficacy of VERU-111 in a Taxane Resistant Human Prostate Cancer Model at the 2018 Genitourinary Cancers Symposium

MIAMI, Feb. 06, 2018 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ:VERU) today announced data from a pre-clinical study of VERU-111, a novel oral alpha and beta tubulin inhibitor, showing potent activity against paclitaxel sensitive and resistant prostate cancer models, that will be presented in a poster session at the 2018 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium to be held February 8-10, 2018, at the Moscone West Building in San Francisco, California. Taxane chemotherapy prolongs survival and improves 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 VERU-111 compared with IV docetaxel in a paclitaxel 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 was well tolerated and the animals gained weight during treatment.

“This exciting data and the unique properties of VERU-111 provide further support for the utility of this oral drug to fill an important clinical unmet need in prostate cancer. Further, this drug has been shown to have 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: Efficacy of VERU-111, an oral alpha and beta tubulin inhibitor, in taxol responsive and resistant prostate cancer models

Poster Session: Poster Session B

Poster Board Number: B13

Date: Friday, February 9, 2018

Additional information on the meeting can be found on the ASCO Genitourinary Cancers Symposium website: https://gucasym.org/.

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 biopharmaceutical company focused on urology and oncology. Veru utilizes FDA's 505(b)(2) regulatory approval pathway to develop and commercialize drug candidates. FDA's 505(b)(2) regulatory approval pathway is designed to allow for potentially expedited, lower cost and lower risk regulatory approval based on a previously established safety and efficacy profile of the product. Veru is developing products under the 505(b)(1) pathway as well, which is the traditional new drug application (NDA) pathway. 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), VERU-722 (fixed ratio clomiphene citrate) for male infertility, 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 Phase1/2 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, the following: product demand and market acceptance; competition in the Company's markets and the risk of new competitors and new competitive product introductions; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; many of the Company's products are at an early stage of development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including licensing risks; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; 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; 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; the Company's reliance on its international partners in the consumer sector and on the level of spending on the female condom 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; risks related to the costs and other effects of litigation; 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.