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Veru Reports Positive Clinical Results from VERU-111 Phase 1b/2 Trial in Men with Metastatic Castration-Resistant Prostate Cancer, Advancing to Pivotal Phase 3 Clinical Program

--VERU-111 Safe and Well Tolerated at Daily Doses 63 mg and Lower; No Significant Neutropenia or Neurotoxicity Observed--

--Evidence of antitumor activity; durable PSA declines, objective tumor regression and stable disease--

--In the eight men who have been treated with at least four 21-day continuous cycles, median duration of tumor response without cancer progression is 10 months (range 6-14 months); 7 of these 8 men are still receiving VERU-111 treatment without evidence of cancer progression--

--VERU-111 Phase 2 clinical study portion is enrolling men who have metastatic castration-resistant prostate cancer and who develop prostate cancer progression while on a novel androgen blocking agent, but prior to chemotherapy--

--Company is advancing VERU-111 and plans to meet with FDA next quarter to gain agreement on registration Phase 3 clinical trial design for VERU-111 in this indication--

MIAMI, May 05, 2020 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer, today provided an update on the clinical results from the fully-enrolled Phase 1b portion of the Phase 1b/2 clinical trial of VERU-111, its first-in-class oral, α and β tubulin inhibitor, in men with metastatic castration-resistant prostate cancer who have become also resistant to a novel androgen blocking agent (abiraterone or enzalutamide). In these men, the androgen receptor targeted approaches have been exhausted. A drug with a different mechanism of action, like VERU-111, is greatly needed for men who have metastatic castration and androgen blocking agent resistant prostate cancer.

The Phase 1b portion of the Phase 1b/2 clinical study enrolled 39 subjects from 7 clinical sites in the United States. A standard 3x3 design was used to establish the maximum

tolerated dose (MTD), to select a recommended clinical dose for Phase 2 study, and to assess preliminary evidence of antitumor activity of VERU-111 in men with metastatic castration-resistant prostate cancer who have also become resistant to at least one novel androgen blocking agent. There are currently no approved drugs for these men, and the only available therapeutic option is off label IV chemotherapy including taxanes (docetaxel and cabazitaxel).

Oral dosing escalated from 4.5mg to 81mg (7 days of dosing followed by 14 days of no drug each 21-day cycle). After no dose limiting toxicity was observed with 7 days of dosing per cycle, the dose was increased in the next cohort of patients. Additionally, the dosing schedule in the patients that had completed the 7 days with 14 days off drug per cycle dosing schedule was expanded to 14 days of dosing with 7 days off drug per cycle, and then to 21 days of dosing with no days off drug per cycle.

Blood levels of VERU-111 were measurable at doses as low as 9 mg per day and VERU-111 drug levels increased with higher doses. As for safety, the MTD of VERU-111 was determined to be 72mg (3 of 11 men had reversible Grade 3 diarrhea). No Grade 3 diarrhea was observed at doses less than 72 mg per day. At doses of VERU-111 of 63 mg and lower per day, mild to moderate nausea, vomiting, diarrhea and fatigue were the most common adverse events. There were no reports of neurotoxicity and no neutropenia at doses 63 mg and lower oral daily dosing continuous for 21 days per cycle.

Efficacy (antitumor activity) was assessed by serum PSA and standard local imaging with bone and CT scans. In the eight men that received at least four 21-day cycles of oral VERU-111 at any dose, based upon their 21-day cycle baseline PSA levels, 6/8 (75%) had decreases in their PSA levels, 4 patients (50%) demonstrated a ≥ 30% decline, and 2 patients (25%) had a ≥ 50% decline in serum PSA. Based upon PCWG3 and Response Evaluation Criteria in Solid Tumors (RECIST) 1.1 criteria, objective tumor responses were seen in 2 patients (25%) (soft tissue and bone) and 5/8 patients (63%) had stable disease. Objective tumor responses and PSA declines lasted longer than 12 weeks. The primary endpoint used in pivotal efficacy studies for the treatment of metastatic castration-resistant prostate cancer is median time to cancer progression by imaging (bone and CT scans). In the current study, median duration of response, or time to cancer progression, has not been reached since 7 out of 8 of the men are still being treated on the study with an average duration of response of 10 months (range = 6-14 months). There are an additional 3 subjects on study that have not yet completed four 21-day cycles; therefore, a total of 10 men are still on study.

“The preliminary evidence of antitumor activity and favorable safety profile of VERU-111 observed in the dose escalation and expansion Phase 1b study is quite encouraging. As predicted most responses occurred around the recommended Phase 2 dose and schedule,” said Mario Eisenberger, MD, R. Dale Hughes Professor of Oncology and Urology at the Johns Hopkins Hospital and a Director at Veru Inc. “All patients at the time of enrollment had evidence of disease progression with at least one novel androgen receptor targeting drug (abiraterone and enzalutamide). The initial clinical experience with VERU-111 appears favorable in the context of other FDA approved cytotoxic drugs (docetaxel and cabazitaxel) in metastatic castration-resistant prostate cancer. As for safety, the lack of neurotoxicity and the lack of significant myelosuppression observed thus far, coupled with the evidence that chronic long-term administration is feasible, strongly support the potential benefits of VERU-

111 over IV cytotoxic taxanes in this setting."

"I am very pleased to update you with the exciting results of our VERU-111 Phase 1b portion of the Phase 1b/2 clinical trial," said Mitchell Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc. "VERU-111 has promising antitumor activity with a good safety profile. The clinical development goal is to position VERU-111, which has a unique drug mechanism of action that does not target the androgen receptor, as the next "go to drug" in men who have metastatic castration-resistant prostate cancer and who have evidence of prostate cancer progression while being treated with an androgen blocking agent like abiraterone or enzalutamide, but prior to using "off label" IV chemotherapy. These clinical results firmly position Veru as an oncology focused biopharmaceutical company. We will meet with FDA next quarter to gain agreement on the registration Phase 3 design for this indication. We also plan to present an update of the Phase 1b/2 clinical data at the next possible upcoming major scientific meeting."

About Veru Inc.
Veru Inc. is an oncology and urology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer. The Veru prostate cancer pipeline includes VERU-111, Zuclomiphene citrate and VERU-100. VERU-111 is an oral, next-generation, first-in-class small molecule that targets and disrupts alpha and beta tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in two portions of an ongoing open label clinical trial – the Phase 1b portion and the Phase 2 portion. The Phase 2 portion targets men who have metastatic castration-resistant prostate cancer who have also become resistant to novel androgen blocking agents, such as abiraterone or enzalutamide, but prior to proceeding to IV chemotherapy -- also referred to as the prechemotherapy stage. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being evaluated for estrogenic activity in a Phase 2 trial (Stage 1 testing placebo, Zuclomiphene 10mg, and Zuclomiphene 50mg) to treat hot flashes, a common side effect caused by androgen deprivation therapy (ADT) in men with advanced prostate cancer. Following an End of Phase 2 meeting with the FDA, the Company plans to advance Zuclomiphene Citrate to a Phase 3 clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes with a potential start date in late calendar year 2020. VERU-100 is a novel, proprietary peptide formulation for ADT with multiple potential beneficial clinical attributes addressing the shortfalls of current FDA-approved ADT formulations for the treatment of advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration --- a problem that occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonists commercially approved beyond a one-month injection. VERU-100 is anticipated to enter a Phase 2 dose-finding study with a potential start date in the third quarter of calendar year 2020.

Veru is also advancing new drug formulations in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFIN®) for the administration of tadalafil 5mg and finasteride 5mg

combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company had a successful pre-NDA meeting with the FDA and the expected submission of the NDA for TADFIN is the fourth quarter of calendar year 2020 or early 2021. Veru is also developing Tamsulosin XR capsules which is a formulation of tamsulosin, the active ingredient in FLOMAX®, which Veru has designed to avoid the “food effect” inherent in currently marketed formulations of the drug, allowing for potentially safer administration and improved patient compliance.

The Company's commercial products include the FC2 Female Condom / FC2 Internal Condom® ("FC2"), an FDA-approved product for the dual protection against unwanted pregnancy and the transmission of sexually transmitted infections, and the PREBOOST® 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The Company’s Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple third party telemedicine and internet pharmacy providers, retail pharmacies, as well as OTC via the Company’s website at www.fc2.us.com. In the global public health sector, the Company markets FC2 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. PREBOOST® is marketed exclusively through online sales in the U.S. under the Roman Swipes brand name by Roman Health Ventures Inc. Roman is a leading telemedicine company that discreetly sells men's health products via the internet website www.getroman.com. To learn more about Veru products please visitwww.verupharma.com.

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and studies due to COVID-19, 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 and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; the risk that the Company's products may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; 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 therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; the risk that the Company's will be affected by regulatory developments, including a reclassification of products; *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; the risk that delays in orders or shipments under government tenders or the Company's U.S. prescription business could cause significant quarter-to-quarter variations in the Company's operating results and adversely affect its net revenues and gross profit; 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 potential disruption of production at the Company's manufacturing facilities and/or of the Company's ability to timely supply product due to labor unrest or strikes, labor shortages, raw material shortages, physical damage to the Company's facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory actions; 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 fiscal year ended September 30, 2019. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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