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Veru Secures FDA Agreement to Initiate Phase 2 Study of VERU-111, Novel Microtubule Depolymerization Drug to Combat COVID-19

--VERU-111's Ability to Disrupt Microtubules has Potential for Dual Drug Action Against COVID-19: Treat SARS-CoV-2 Virus Infection and Reduce Inflammation Caused by Viral Infection-Induced Cytokine Storm--

--Phase 2 Clinical Study Expected to Commence in Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome in 2 Weeks--

MIAMI, May 12, 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 announced that it has received FDA permission to initiate a Phase 2 clinical trial to assess the efficacy of VERU-111, a microtubule depolymerization agent, in combating COVID-19, the global pandemic disease caused by the novel coronavirus SARS-CoV-2.

VERU-111 is an oral, first-in-class microtubule depolymerization agent that targets the colchicine binding site of a and b tubulin subunits to inhibit microtubules and is currently under clinical development in prostate cancer. Drugs that target microtubules have broad antiviral activity by disrupting the intracellular transport of viruses such as SARS CoV-2, along microtubules. Microtubule trafficking is critical for viruses to cause infection. Furthermore, microtubule depolymerization agents that target a and b tubulin subunits of microtubules also have strong anti-inflammatory effects including the potential to treat the cytokine release syndrome (cytokine storm) induced by the SARS-CoV-2 viral infection that seems to be associated with high COVID-19 mortality rates.

The Company met with FDA and received agreement on the clinical development program for VERU-111 as a potential dual antiviral and anti-inflammatory agent to combat COVID-19 under the new FDA program--Coronavirus Treatment Acceleration Program (CTAP).

The Phase 2 clinical trial is a double-blind randomized (1:1) placebo-controlled trial evaluating daily oral doses of VERU-111 versus placebo for 21 days in 40 hospitalized patients (VERU-111 20 subjects and placebo 20 subjects) who tested positive for the SARS-CoV-2 virus and are at high risk for Acute Respiratory Distress Syndrome (ARDS). The

primary efficacy endpoint will be the proportion of patients that are alive and without respiratory failure at Day 29. Secondary endpoints include the measured improvements on the WHO Disease Severity Scale (8-point ordinal scale) which captures COVID-19 disease symptoms and signs including hospitalization to progression of pulmonary symptoms to mechanical ventilation as well as death. The study is expected to commence in the next 2 weeks.

VERU-111 has been shown to be well tolerated in the Phase 1b clinical study of 39 men as recently reported. VERU-111 is currently being administered as a 63mg daily dose in the ongoing Phase 2 clinical trial in men with metastatic castration resistant prostate cancer. The Phase 2 COVID-19 study will evaluate an 18mg oral daily dosing single treatment for 21 days.

“VERU-111 has demonstrated promising anticancer activity and a good safety profile in the recently completed Phase 1b metastatic castration resistant prostate cancer trial. We are now actively enrolling men into our Phase 2 prostate cancer clinical trial. Although Veru is focused in prostate cancer and oncology, due to the urgency of the current global pandemic and the fact that VERU-111 has the potential to treat both SARS-CoV-2 infection and the associated reactive severe lung inflammation in COVID-19 patients at high risk for ARDS, the Company is duty-bound to pursue this COVID-19 indication even though it is not the primary focus of the Company,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Based on the strong pharmacologic rationale as well as the preclinical and clinical studies supporting that VERU-111 may have both antiviral and anti-inflammatory effects along with acceptable safety against the SARS-CoV-2 virus, we will initiate this placebo controlled Phase 2 study in patients that have been hospitalized for SARS-CoV-2 at high risk for ARDS to improve symptoms and recovery and to avoid the need for mechanical ventilation. We plan to dose the first patient in the next 2 weeks,” said Dr. Steiner.

Because of the urgent need for effective and timely therapeutics to combat COVID-19, the Company has applied for significant grant funding through both The Biomedical Advanced Research and Development Authority of the US Department of Health and Human Services (BARDA) and The Defense Advanced Research Projects Agency of the US Department of Defense (DARPA) to expedite the clinical development program of VERU-111 for COVID-19. There is no guarantee that such grant funding will be provided.

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. VERU-

111 will also be evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19. 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.

"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 regarding the expected timing of clinical trials for the treatment of COVID-19 using VERU-111, the therapeutic potential for VERU-111 to treat COVID-19, the Company's request for funding from BARDA and DARPA in connection with its COVID-19 clinical trial, the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, and clinical study results including potential benefits and the absence of adverse events. 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. 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, including potential delays in the recruitment of patients and their ability to effectively participate in such trials 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; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; 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 and subsequent quarterly reports on Form 10-Q. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.

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Source: Veru Inc.