August 4, 2020

VERU-111 Suppresses Key Cytokines Responsible for Severe Acute Respiratory Distress Syndrome in COVID-19

--VERU-111 significantly reduced key cytokines involved in Acute Respiratory Distress Syndrome in COVID-19 in a toxic shock model--

--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 in hospitalized COVID-19 patients at high risk for Acute Respiratory Distress Syndrome actively enrolling patients --

MIAMI, Aug. 04, 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 confirmed in an *in vitro* study that VERU-111 has anti-inflammatory action against the key cytokines involved in the cytokine storm triggered by the SARS-CoV-2 infection.

In critically ill patients with COVID-19, SARS-CoV-2 infection triggers an overwhelming release of immune proteins called cytokines referred to as a cytokine storm. The cytokine storm may lead to acute respiratory distress syndrome (ARDS), acute renal failure, blood clots, multi-organ failure, shock, heart arrhythmias, and death. Key cytokines released during the storm and detected in high levels in the blood from COVID-19 patients include interleukin (IL)-1α, IL-1ß, IL-6, IL-8, and Tumor Necrosis Factor α (TNFα).

VERU-111 is an oral, first-in-class microtubule depolymerization agent that has potentially both antiviral and anti-inflammatory dual action to broadly treat the cytokine storm which is associated with high COVID-19 mortality rates.

An *in vitro* study was conducted by a team of researchers at the University of Tennessee Health Science Center (Ms. Rui Wang, Ms. Patricia Wheller, Dr. Arnold Postlethwaite and Dr. Wei Li) to determine if VERU-111 can suppress toxic shock levels of these key cytokines of the cytokine storm. The effects of VERU-111 on cytokine production was assessed by stimulating isolated mouse spleen cells with an endotoxin that causes shock called lipopolysaccharide (LPS). The cells were stimulated with 5 µg/ml LPS for 1 hour and then incubated overnight (approximately 21 hours) with VERU-111 to mimic the clinical situation,

and cytokine levels were analyzed.

At a concentration that represents the blood levels of VERU-111 observed in clinically dosed patients, VERU-111 (40 nM) significantly reduced the production of key cytokines known to be involved with COVID-19 cytokine storm: TNFα (-31%) ($p=0.006$), IL-1α (-123%) ($p=0.0005$), IL-1β(-97%) ($p=0.0003$), IL-6 (-85%) ($p<0.00008$), and IL-8 homologue (-96%) ($p<0.0000007$). This reduction was similar to, or greater than, depending on the specific cytokine, to that observed with dexamethasone (10nM), a steroid and a known inhibitor of cytokine production during inflammation.

Suppression of these key cytokines may be an effective way to prevent clinical deterioration of patients with COVID-19 to ARDS. Veru is currently enrolling a double-blind randomized (1:1) placebo-controlled Phase 2 clinical trial evaluating daily oral doses of VERU-111 versus placebo for 21 days in 40 hospitalized patients who tested positive for the SARS-CoV-2 virus and are at high risk for ARDS. The primary efficacy endpoint will be the proportion of patients that are alive and without respiratory failure at Day 22. 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.

“Although Veru is focused on prostate cancer and oncology, due to the urgency of the current global pandemic and the need for effective drugs against COVID-19, 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 having antiviral activity, and now confirmed in this *in vitro* study that VERU-111 also has the ability to suppress key cytokines in COVID-19 patients, we are even more hopeful that VERU-111 should show in the Phase 2 study with COVID-19 patients at high risk for ARDS, an improvement in patient outcomes.”

Dr. Steiner added, “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 nearing completion of enrollment into our Phase 2 prostate cancer clinical trial. This current cytokine study also further supports the use of VERU-111 in prostate cancer as cytokines IL-6, IL-1, and IL-8 appear to play key roles in the promotion of prostate cancer progression, metastases, and drug resistance. The ability of VERU-111 to suppress these cytokines may benefit men who have metastatic castration resistant prostate cancer which is the primary indication that VERU-111 is being developed for.”

Veru Inc. has a sponsored research agreement with the University of Tennessee and a consulting agreement with Dr. Wei Li. In addition, as a co-licensor of VERU-111, the University of Tennessee Research Foundation would receive compensation from the commercialization of VERU-111.

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, VERU-100, and Zuclomiphene citrate. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules. VERU-111 is being evaluated in an open label Phase 1b/2 clinical study in men with metastatic castration and androgen receptor targeting agent resistant

prostate cancer. The Phase 1b clinical study completed enrollment of 39 men and is ongoing. The Phase 2 clinical study is enrolling approximately 40 men who have metastatic castration resistant prostate cancer and who have also become resistant to at least one of the novel androgen receptor targeting agents, such as abiraterone or enzalutamide, but prior to proceeding to IV chemotherapy. VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19. VERU-100 is a novel, proprietary peptide formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT) for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist administered as a small volume, subcutaneous 3-month depot injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration --- a problem which 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. A Phase 2 study to evaluate VERU-100 dosing is anticipated to begin in the fourth quarter of calendar year 2020. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by 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.

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 and retail pharmacies. 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 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 visit www.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 studies for the treatment of COVID-19 using VERU-111, the therapeutic potential for VERU-111 to treat COVID-19, 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; the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial; 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, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment; 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.