March 1, 2021

# Veru Receives FDA Agreement to Advance VERU-111 into Phase 3 Study in Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome (ARDS)

**– Veru completes expedited end of Phase 2 trial meeting with FDA –**

**– FDA agrees that Phase 2 clinical findings suggest a clinically meaningful benefit for the use of VERU-111 in hospitalized COVID-19 patients at high risk for ARDS –**

**– FDA agrees to advance VERU-111 into Phase 3 clinical study in hospitalized high risk COVID-19 patients to confirm the potential benefit and risk –**

**– Phase 3 clinical study expected to begin in April 2021 with clinical results expected in calendar Q4 2021 –**

MIAMI, March 01, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company, today announced that the FDA agreed in an End of Phase 2 meeting, to advance VERU-111 into a Phase 3 registration clinical study based on the clinically meaningful benefits observed with VERU-111 treatment in the recently completed double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating oral, once-a-day dosing of VERU-111 versus placebo in approximately 40 hospitalized COVID-19 patients at high risk for ARDS. The Phase 2 trial demonstrated clinically meaningful reductions in relevant endpoints, including respiratory failure, patient mortality, days in the ICU and days on mechanical ventilation. VERU-111 has the potential for two-pronged action against COVID-19 as an antiviral and an anti-inflammatory agent which is supported by positive Phase 2 clinical study results.

“We are very pleased with the outcome of the FDA meeting. FDA was extremely collaborative and thought that the clinical data from the Phase 2 were promising and suggest a potential clinically meaningful benefit for the use of VERU-111 in hospitalized high risk COVID-19 patients. Also, the FDA agreed that VERU-111 warrants further development in a Phase 3 program,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Due to the urgency of the global pandemic and need for more effective treatment options for patients, we remain duty-bound to pursue this indication, even though it has not been the primary focus of Veru. We have the resources to conduct a Phase 3 trial without impacting our cancer drugs’ clinical development.”

We have met with and will seek funding from The Biomedical Advanced Research and Development Authority of the US Department of Health and Human Services (BARDA) as well as other agencies to fund the estimated amount of commercial drug to supply the needs of the US population, assuming confirmatory positive Phase 3 clinical results and FDA approval.

**Phase 3 Clinical Trial Design:**

With a similar trial design to the completed positive Phase 2 study, the Phase 3 clinical registration trial design will evaluate daily oral doses of VERU-111 versus placebo with the primary efficacy endpoint of proportion of patients alive at Day 29. It is expected that the Phase 3 clinical trial will be conducted in approximately 400 hospitalized patients who have SARS-CoV-2 virus infection and are at high risk for ARDS at a 2:1 ratio between the VERU-111 (approximately 267 patients) and placebo (approximately 133 patients) treated groups.

The Company has enough clinical drug supply on hand to complete the Phase 3 clinical study. The Phase 3 clinical trial is expected to commence in April 2021 and clinical results are expected by the fourth quarter of calendar year 2021.

**About the Phase 2 COVID-19 Clinical Trial:**

Veru conducted a double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating oral, once-a-day dosing of VERU-111 18mg versus placebo in approximately 40 hospitalized COVID-19 patients who were at high risk for ARDS. The trial was conducted in five sites across the United States. Patients hospitalized with documented evidence of COVID-19 infection and at high risk for ARDS were enrolled. Subjects received an 18mg dose of VERU-111 or placebo, as well as standard of care for 21 days or until released from hospital. The primary efficacy endpoint was the proportion of patients alive without respiratory failure at Day 29.

*Clinical Efficacy and Safety Results:*

For the primary endpoint in a modified intent-to-treat (MITT) population, VERU-111 treatment compared to placebo had a statistically significant and clinically meaningful reduction in the proportion of patients who are treatment failures (dead or alive with respiratory failure) with a 30% treatment failure rate in the placebo group (n=20) compared to 5.6% in the VERU-111 treated group (n=18) at Day 29. This represents an 81% relative reduction in the VERU-111 treatment failures and showed statistical significance with p=0.05.

For secondary endpoints: in the Intent to Treat (ITT) population, VERU-111 reduced the proportion of patients who died on study from 30% (6/20) in the placebo group to 5.3% (1/19) in the VERU-111 treated group (p=0.044). This is an 82% relative reduction in mortality in the VERU-111 treated group. In an MITT population, VERU-111 showed a statistically significant and clinically meaningful reduction in days in ICU (VERU-111 patients at 3.00 ± 7.16 days versus placebo 9.55 ± 11.54; p=0.04). VERU-111 reduced the days on mechanical ventilation from an average of 5.4 days in the placebo group to 1.6 days in the VERU-111 treated group. VERU-111 was tolerated with a good safety profile.

*VERU-111 and Standard of Care*

During the study, the standard of care included treatment with remdesivir and/or dexamethasone under an Emergency Use Authorization. The use of remdesivir and dexamethasone did not have a significant effect on patient outcomes in the study. A subgroup analysis of patients that received standard of care was conducted. There were six patients in the entire study that did not receive standard of care of either remdesivir or dexamethasone (four in the VERU-111 treated group and two in the placebo group). In patients that did not receive the standard of care, VERU-111 treatment resulted in a statistically significant reduction in days in ICU (VERU-111 1.43 ± 3.96 days versus placebo 8.83 ± 13.07 days; p=0.024) and days on mechanical ventilation (VERU-111 zero days versus placebo 6.00 ± 10.57 days; p=0.0427). In the VERU-111 group on standard of care, no patient required mechanical ventilation on study.

**About Veru Inc.**

Veru Inc. is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer and breast 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 for the treatment of metastatic castration and androgen receptor resistant prostate cancer. 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. 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. The Veru breast cancer pipeline includes enobosarm for AR+/ER+/HER2- metastatic breast cancer and VERU-111 for taxane resistant metastatic triple negative breast cancer. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets and activates the androgen receptor in AR+/ER+/HER2- metastatic breast cancer without unwanted masculinizing side effects. VERU-111 is also being advanced into Phase 3 for the treatment of hospitalized patients with COVID-19 who are at high risk for acute respiratory distress syndrome.

The Company's Sexual Health Business commercial product is the FC2 Female Condom®/ FC2 Internal Condom ("FC2"), an FDA-approved product for the dual protection against unintended pregnancy and the transmission of sexually transmitted infections. 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. An NDA was submitted in February 2021 for TADFIN™ (tadalafil 5mg and finasteride 5mg) capsule 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®). If approved, revenues from TADFIN™ (tadalafil 5mg and finasteride 5mg) capsule and the current revenues from the FC2 business will be combined in our sexual health commercial business. 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,whether funding from BARDA or other agencies will be forthcoming, the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated design and scope of the clinical trial, the anticipated timeframe for clinical studies and FDA submissions, clinical study results including potential benefits and the absence of adverse events, and our resources to conduct clinical trials. 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 and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; 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 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 and third party 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 and third party 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, 2020 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](www.verupharma.com/investors).*

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