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Veru Reports Positive Phase 2 Clinical Results of VERU-111 in Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome

– Potential for two-pronged action against COVID-19 as an antiviral and anti-inflammatory agent supported by Phase 2 clinical study results –

– Primary efficacy endpoint in hospitalized patients shows VERU-111 treatment had statistically significant 81% relative reduction in death or respiratory failure at Day 29 –

– Statistically significant 82% relative reduction in patient mortality versus placebo–

– Statistically significant reduction in days in ICU; there was also a decrease in days on mechanical ventilation–

– Oral daily dosing well tolerated with no treatment-related adverse events –

– Granted expedited meeting with FDA to discuss Phase 3 trial design and meeting with BARDA to discuss potential funding; Phase 3 clinical study expected to begin in April 2021 with clinical results expected in calendar Q4 2021 –

– Company to host an investor conference call at 9:00 am ET today to discuss results and next steps –

MIAMI – February 8, 2021 – Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company, today announced positive efficacy and safety results from a double-blind, randomized, placebo-controlled Phase 2 clinical trial evaluating oral, once-a-day dosing of VERU-111 versus placebo in approximately 40 hospitalized patients at high risk for Acute Respiratory Distress Syndrome (ARDS) from SARS-CoV-2.

"We are very pleased with the results of our Phase 2 trial, which demonstrated clinically meaningful reductions in relevant endpoints, including respiratory failure, days in the ICU and on mechanical ventilation and patient mortality. We believe VERU-111 has significant potential in treating COVID-19,

both as a broad-spectrum antiviral and an anti-inflammatory agent, helping to prevent the effects that lead to ARDS and death," 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 are 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 look forward to our upcoming discussion with FDA concerning the regulatory and clinical development steps to move VERU-111 for COVID-19 forward."

"We are in critical need of effective drugs in high-risk COVID-19 patients. The slow rollout of COVID-19 vaccines, the emergence of new mutant COVID-19 strains and the lack of truly effective drugs in hospitalized, high-risk patients make it critical that we advance VERU-111 and confirm these impressive results in a Phase 3 clinical study as quickly as possible," said Alan Skolnick, M.D., Principal Investigator with HD Research, who conducted the trial at Memorial Hermann Memorial City Medical Center in Houston TX. "The results of the Phase 2 trial were strengthened by the strict parameters in place, which included a blinded, placebo-controlled, randomized study that also allowed standard of care for both the treated and the placebo groups in hospitalized patients at high risk for ARDS."

Trial Design:

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 Acute Respiratory Distress Syndrome (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. Respiratory failure was defined as endotracheal intubation and mechanical ventilation, extracorporeal membrane oxygenation, high-flow nasal cannula oxygen delivery, noninvasive positive pressure ventilation, and/or clinical diagnosis of respiratory failure with initiation of none of these measures only when clinical decision making is driven solely by resource limitation.

Clinical Efficacy and Safety Results:

For the primary endpoint in hospitalized patients that had >1 dose of study drug, 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 a 5.6% in the VERU-111 treated group (n=18) at Day 29. This represents an 81% relative reduction in treatment failures and showed statistical significance with p=0.05.

Subgroup analyses of treatment failures (dead or alive with respiratory failure) in patients at high risk for ARDS:

Age: older patients, an analysis of >60 years of age diagnosed with COVID-19 who are at higher risk for death and respiratory failure: Treatment failures were 9% for VERU-111 versus 50% for placebo; p=0.046.

Severity of COVID-19, an analysis of patients with a WHO Score of Disease Severity ≥5 (hospitalized; on oxygen) at baseline: Treatment failures were 11% for VERU-111 versus 54% for placebo; p=0.04.

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 a 82% relative reduction in mortality in the VERU-111 treated group.

In patients that received >1 dose of VERU-111 or placebo, 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). Additionally, the proportion of patients in the ICU for ≥3 days on study was significantly lower (VERU-111 at 28%, versus placebo, 60%; p=0.046).

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 received 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.

As expected, the severity of the COVID-19 infection at baseline, as measured by the WHO scale, was a significant predictor of patient outcomes. The disease severity at baseline was not different between the treatment groups.

Regulatory Discussions and Further Study

The Company has been granted an expedited end-of-Phase 2 meeting with the FDA to discuss next steps, including a Phase 3 clinical registration trial design for the VERU-111 COVID-19 program. The Company expects that this confirmatory study will have a similar trial design to the Phase 2 study to evaluate daily oral doses of VERU-111 versus placebo with the primary efficacy endpoint of proportion of patients alive without respiratory failure at Day 29. It is expected that the Phase 3 clinical trial will be conducted in approximately 200 hospitalized patients who have SARS-CoV-2 virus infection and are at high risk for Acute Respiratory Distress Syndrome.

The Company has enough clinical drug supply on hand to complete the Phase 3 clinical study. Once agreed upon by FDA, the Phase 3 is expected to commence in April 2021 and conclude by the fourth quarter of calendar 2021. We will seek funding from The Biomedical Advanced Research and Development Authority of the US Department of Health and Human Services (BARDA) and other

agencies to fund the estimated amount of commercial drug to supply the needs of the US population, assuming confirmatory positive clinical results and FDA approval.

BARDA has granted Veru a meeting to discuss possible grant funding for the Phase 3 study and manufacturing scale up.

Investor Event Details

Veru Inc. will host a conference call today at 9:00 am ET to discuss the positive clinical results from the Phase 2 trial. Interested parties may access the call by dialing 1-412-902-6703 and entering the participant access code number 1310812 to enter the conference. The call will also be available through a live audio broadcast via the Internet at www.verupharma.com. A playback of the call will be archived and accessible on the same website for at least three months. A telephonic replay of the conference call will be available later that day by dialing 1-877-344-7529 for U.S. callers, or 1-412-317-0088 from outside the U.S., replay access code 10152256, for one week.

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. 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 hormone sensitive metastatic ER+/HER2- metastatic breast cancer and VERU-111 for taxane resistant metastatic triple negative breast cancer (TNBC). Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor in AR+/ER+/HER2- metastatic breast cancer without unwanted virilizing side effects. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules and is not a substrate for P-glycoprotein drug resistance protein. 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 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. These documents are available on the "SEC Filings" section of our website at www.verupharma.com/investors.