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Veru Enrolls First Patient in Phase 3 Clinical Trial of Sabizabulin (VERU-111) in High Risk Hospitalized COVID-19 Patients

—Sabizabulin is a novel oral agent with both anti-viral and anti-inflammatory activities —

—Sabizabulin treatment reduced mortality in hospitalized COVID-19 patients at high risk for Acute Respiratory Distress Syndrome in Phase 2 study—

—Enrollment is expected to be completed by calendar Q4 2021—

MIAMI, May 19, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancer, today announced that it has enrolled the first patient in its Phase 3 clinical trial of sabizabulin, a novel, proprietary, oral cytoskeleton disruptor with anti-inflammatory and anti-viral properties, to combat the effects of COVID-19, the global pandemic disease caused by the novel coronavirus SARS-CoV-2.

“COVID-19 infection rates and hospitalizations are still at serious levels. There are mutating and double mutating virus strains, and large parts of the population either unable or unwilling to get access to effective vaccines. In fact, global cases of COVID-19 are at the highest levels since the start of the pandemic. It is clear that an effective and safe oral therapeutic that prevents deaths in hospitalized patients with moderate to severe COVID-19 disease who are at risk for Acute Respiratory Distress Syndrome (ARDS) is desperately needed,” said Mitchell Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc. “We strongly believe that sabizabulin with its anti-inflammatory and anti-viral properties and its favorable safety profile can be that greatly needed oral therapy. With the aim of meeting our recruitment goals by year end, we have selected clinical sites in locations that have been hard hit by COVID-19 in the US, Brazil, Argentina, Colombia, and Mexico.”

Sabizabulin (VERU-111) Phase 3 Trial Design

The Phase 3 clinical trial is a double-blind, multicenter, multinational, randomized (2:1), placebo-controlled trial evaluating daily oral doses of 9mg sabizabulin for up to 21 days versus placebo in 300 hospitalized patients (200 subjects will be treated with sabizabulin and 100 subjects will receive placebo/standard of care) who tested positive for the SARS-CoV-2 virus and who are at high risk for ARDS. Because of better oral bioavailability, the systemic blood levels from the 9mg sabizabulin dosage are similar to the 18mg sabizabulin formulation used in the Phase 2 clinical study. Subjects in the sabizabulin and placebo arms

will also be allowed to receive standard of care. The primary efficacy endpoint will be the proportion of patients that die on study up to Day 60. Secondary endpoints will include the proportion of patients without respiratory failure, days in ICU, WHO Ordinal Scale for Clinical Improvement change from baseline, days on mechanical ventilation, days in the hospital, and viral load. The study will be conducted in the United States, Brazil, Argentina, Mexico, and Colombia. Enrollment is targeted to be completed by year-end.

About Sabizabulin (VERU-111) as a Therapeutic for COVID-19
Sabizabulin is a cytoskeleton disruptor which by causing microtubule depolymerization has both anti-viral and anti-inflammatory activity and could be effective against the SARS-CoV-2 virus by disrupting its intracellular transport along the microtubules. Microtubule trafficking is critical for viruses to be transported, replicated, assembled, and released from the cell. In addition, microtubule depolymerization drugs that target the “colchicine binding site” of microtubules, like sabizabulin, also have strong anti-inflammatory effects, including the potential to treat the cytokine release syndrome (cytokine storm) and septic shock induced by the SARS-CoV-2 viral infection that is associated with high COVID-19 mortality rates.

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 sabizabulin versus placebo in 39 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 sabizabulin 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 hospitalized patients (a modified intent-to-treat (MITT) population), sabizabulin treatment compared to placebo had a 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 sabizabulin treated group (n=18) at Day 29. This represents an 81% relative reduction in the sabizabulin treatment failures.

For secondary endpoints: in the Intent to Treat (ITT) population, sabizabulin reduced the proportion of patients who died on study from 30% (6/20) in the placebo group to 5.3% (1/19) in the sabizabulin treated group (p=0.044). This is an 82% relative reduction in mortality in the sabizabulin treated group. In a MITT population, sabizabulin showed a statistically significant and clinically meaningful reduction in days in ICU (sabizabulin patients at 3.00 ± 7.37 days versus placebo 9.55 ± 12.56; p=0.04). Sabizabulin reduced the days on mechanical ventilation from an average of 5.4 days in the placebo group to 1.6 days in the sabizabulin treated group. Sabizabulin was tolerated with a good safety profile.

Sabizabulin (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

eleven patients in the entire study that did not receive standard of care of either remdesivir or dexamethasone (six in the sabizabulin treated group and five in the placebo group). In patients that did not receive the standard of care, sabizabulin treatment resulted in a statistically significant reduction in days in ICU (sabizabulin 0 days versus placebo 9.53 ± 12.56 days; p=0.014) and days on mechanical ventilation (sabizabulin zero days versus placebo 3.93 ± 8.74 days). In the sabizabulin group on standard of care, no patient required ICU admission or 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. Veru's prostate cancer pipeline includes: sabizabulin, an oral, first-in-class, new chemical entity that targets the cytoskeleton disruptor which in prostate cancer also disrupts androgen receptor transport, is expected to commence this month a Phase 3 VERACITY clinical trial in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer. VERU-100, a novel, proprietary GnRH antagonist peptide long acting 3-month subcutaneous injection formulation for androgen deprivation therapy, is expected to start the planned Phase 2 clinical study this month and the Phase 3 clinical study is planned to initiate in Q4 2021 to treat hormone sensitive metastatic prostate cancer. Veru's breast cancer pipeline includes: enobosarm, an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets and activates the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects; Phase 3 ARTEST clinical trial to evaluate enobosarm in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- advanced breast cancer who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor is anticipated to commence Q2 2021. In a separate clinical development program, a Phase 2 study to evaluate the efficacy and safety of enobosarm in combination with CDK 4/6 inhibitor (abemaciclib) compared to estrogen receptor blocking agent (Active Control) for the treatment of AR+ER+HER2- metastatic breast cancer in a 2nd line metastatic setting in approximately 106 patients who have failed an estrogen receptor blocking agent plus a CDK 4/6 inhibitor (palbociclib) is expected to commence in calendar Q3 2021. Sabizabulin is also being evaluated in a three arm Phase 2b clinical study in calendar Q3 2021 to evaluate oral daily dosing of sabizabulin monotherapy, TRODELVY® monotherapy, and sabizabulin + TRODELVY combination therapy in approximately 200 women with metastatic triple negative breast cancer that have become resistant to at least 2 systemic chemotherapies including a taxane. Based on positive Phase 2 results on the reduction of mortality, sabizabulin is also being evaluated in a Phase 3 trial in approximately 300 subjects 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® (internal condom) ("FC2"), an FDA-approved product for 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. The second potential product, if approved, expected for the Sexual Health Business is 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). An NDA was filed by FDA in April 2021 with a PDUFA date in December 2021. To learn more about Veru products, please visit www.verupharma.com.

Forward-Looking Statements

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 potential of sabizabulin to combat COVID-19 and prevent deaths in patients with moderate to severe COVID-19 disease who are at risk for ARDS, whether future clinical development and results will demonstrate sufficient efficacy and safety to secure FDA approval of the Company's drug candidate, whether sabizabulin will serve any unmet need, what dosage of sabizabulin, if any, might be approved for use in the US or elsewhere, and whether the enrollment timelines will be met, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline.

These forward-looking statements are based on the Company's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the development of the Company's product portfolio and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials and the ability to enroll subjects in accordance with planned schedules; the ability to fund planned clinical development; the timing of any submission to the FDA and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities possibly taking actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the Company's existing products and any future products, if approved, possibly not being commercially successful; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers, commercial efforts, and business development operations; the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations; demand for, market acceptance of, and competition against any of the Company's products or product candidates; new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; changes in regulatory practices or policies or government-driven healthcare reform efforts, including pricing pressures and insurance coverage and reimbursement changes; the Company's ability to successfully commercialize any of its products, if approved; the Company's ability to protect and enforce its intellectual property; the potential 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; 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; the concentration of accounts receivable with our largest customers and the collection of those receivables; 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; 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 from time to time 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. The Company disclaims any intent or obligation to update these forward-looking statements.

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