January 31, 2022

Veru Announces FDA Grant of Fast Track Designation for Sabizabulin for the Treatment of Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome

-- Phase 3 Sabizabulin COVID-19 Clinical Study for Treatment of Hospitalized Moderate to Severe COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome Being Conducted in US, Mexico, South America, and Europe; Clinical Results Expected 1H 2022 --

-- Second Veru Drug Under Development to Receive FDA Fast Track Designation this Month --

MIAMI, Jan. 31, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU) today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Phase 3 registration program for the investigation of sabizabulin, a novel, proprietary, oral cytoskeleton disruptor with both anti-viral and anti-inflammatory properties, to combat COVID-19 infection and the cytokine storm that is responsible for Acute Respiratory Distress Syndrome (ARDS) and death. FDA Fast Track Designation is intended to expedite the development and review of new drugs to treat serious medical conditions that fill unmet medical needs. The global pandemic disease caused by the novel coronavirus SARS-CoV-2 is entering its 3rd year, and there remains an unmet medical need for new effective treatments for hospitalized patients with moderate to severe COVID-19 symptoms at high risk for ARDS and death.

“We are very pleased that the sabizabulin therapeutic for COVID-19 clinical program has received Fast Track designation from the FDA, a distinction that underscores the urgent need for new, novel, effective therapies to be used along with vaccinations to combat this COVID-19 pandemic,” said Mitchell Steiner, MD, Chairman, President and Chief Executive Officer of Veru Inc.

Dr. Steiner added: “COVID-19 global cases, hospitalizations, and deaths are at the highest levels since the start of the pandemic. Some of the antibody drugs are not effective against the omicron variant. 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 high risk for ARDS is desperately needed. We strongly believe that sabizabulin with its anti-viral and anti-

inflammatory properties and a favorable safety profile can be that greatly needed oral therapy for hospitalized COVID-19 patients with serious illness. We look forward to ongoing, productive regulatory interactions with the FDA, which are further enabled with this designation."

About Fast Track Designation
Fast Track designation aims to expedite the development and review of new drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to fill unmet medical needs. The purpose is to get important new drugs to patients faster. Filling an unmet medical need is defined as providing a therapy where none exists or providing a therapy which may be potentially better than available therapy. Drugs that are granted this designation are given the opportunity for more frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval: more frequent written communication with FDA about such things as the design of the proposed clinical trials and use of biomarker; Eligibility for *Accelerated Approval and Priority Review, if relevant criteria are met;* and, *Rolling Review*, which means that a drug company can submit completed sections of its New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. NDA review usually does not begin until the drug company has submitted the entire application to the FDA.

About Sabizabulin for COVID-19
Microtubule trafficking is critical for viruses to be transported, replicated, assembled, and released from the cell. Microtubules also play a role in the inflammatory process including the cytokine release syndrome (cytokine storm). Sabizabulin is a cytoskeleton disruptor which blocks microtubule trafficking and has the potential to treat both the SARS-CoV-2 viral infection and the cytokine storm and septic shock that leads to ARDS and the high COVID-19 mortality rates.

About the Sabizabulin for COVID-19 Phase 3 Trial
The Phase 3 clinical trial is a double-blind, multicenter, multinational, randomized (2:1), placebo-controlled trial evaluating daily oral doses of 9 mg sabizabulin for up to 21 days versus placebo in 300 hospitalized patients (200 subjects treated with sabizabulin and 100 subjects receive placebo/standard of care) who have SARS-CoV-2 virus infection and who are at high risk for ARDS. 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 is being conducted in the United States, Brazil, Argentina, Mexico, Colombia and Bulgaria. Clinical results are expected in the first half of calendar year 2022.

About Veru Inc.
Veru is an oncology biopharmaceutical company with a principal focus on developing novel medicines for the management of breast and prostate cancers.

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor.

Current studies on the two drugs include:

- Enrolling Phase 3 ARTEST study of enobosarm in androgen receptor positive, estrogen receptor positive, and human epidermal growth factor receptor two negative (AR+ ER+ HER2-) metastatic breast cancer with AR ≥ 40% (third-line metastatic setting), and which has been granted Fast Track designation by the FDA.
- Planned Q1 2022 Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (second-line metastatic setting).
- Planned Q1 2022 Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% (third-line metastatic setting).

The Company has determined that patients who have ≥ 40% androgen receptor nuclei staining by immunohistochemistry in their breast cancer tissue, a measure of AR expression, are most likely to respond to enobosarm. Consequently, Veru is developing a companion diagnostic to determine a patient's androgen receptor expression status, and has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostics, which will develop and, if it is approved, commercialize the companion AR diagnostic.

Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

Current studies on these drugs include:

- Enrolling Phase 3 VERACITY and ongoing Phase 2 studies of sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy.
- Enrolling Phase 2 dose-finding study of VERU-100 in advanced hormone-sensitive prostate cancer.
- Planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer undergoing androgen deprivation therapy who suffer from hot flashes.

In addition, sabizabulin, which has dual anti-viral and anti-inflammatory effects, is currently enrolling in a Phase 3 study for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome, also known as the cytokine storm.

Veru also has a commercial sexual health division, the proceeds of which help fund its drug development programs, comprised of:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia, for which commercialization launch plans are underway.
- FC2 Female Condom® (internal condom), for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections which is sold in the U.S. and globally.

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 whether future clinical development and results, including whether sabizabulin will be an effective therapy for hospitalized COVID-19 patients, will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic, the

anticipated design and scope for clinical trials and FDA acceptance of such design and scope, whether any accelerated regulatory pathways, including Fast Track designation, to secure FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are available, when clinical results from the ongoing sabizabulin COVID-19 Phase 3 trial will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need, what dosage, if any, might be approved for use in the US or elsewhere, and whether the commencement or enrollment timelines for the clinical trials and development of the companion diagnostic will be met, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, including the ability of the Company to successfully launch ENTADFI, whether and when enobosarm will be approved by FDA for the treatment of certain breast cancers and the timing of the Company's submissions to FDA and FDA's review of such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm or other drug candidates will be replicated in the current and planned clinical development program for such drug candidate and whether any such properties will be recognized by the FDA in any potential approvals and labeling; when commercial launch of ENTADFI will occur; the magnitude of any potential revenues generated by ENTADFI; whether the Company's current or future clinical development program results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates; and whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use. 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; including 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 or commercialize a product candidate in the U.S.; 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, 2021 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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