April 11, 2022

Veru's Novel COVID-19 Drug Candidate Reduces Deaths by 55% in Hospitalized Patients in Interim Analysis of Phase 3 Study; Independent Data Monitoring Committee Halts Study Early for Overwhelming Efficacy

-- Independent Data Monitoring Committee Unanimously Recommends that Phase 3 Clinical Trial for Sabizabulin for Treatment of Hospitalized COVID-19 Patients at High Risk for ARDS Be Stopped Early Due to Overwhelming Evidence of Efficacy --

-- Sabizabulin Treatment Showed Statistically Significant and Clinically Meaningful 55% Reduction in Deaths Compared to Placebo in Moderate-Severe Hospitalized Patients (p=0.0029) --

-- Sabizabulin Oral Daily Dosing was Well Tolerated with a Similar Safety Profile Compared to Placebo --

-- Company to Meet with FDA to Seek Emergency Use Authorization --

--The Company will Host a Conference Call at 8:00 am ET to Discuss Results and Planned Next Steps --

MIAMI, April 11, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company, today announced positive efficacy and safety results from a planned interim analysis of the double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial evaluating oral sabizabulin 9 mg versus placebo in 150 hospitalized COVID-19 patients at high risk for Acute Respiratory Distress Syndrome (ARDS). The Independent Data Safety Monitoring Committee unanimously recommended that the Phase 3 study be halted early due to efficacy, and they further remarked that no safety concerns were identified.

Phase 3 COVID-19 Trial Design

The Phase 3 COVID-19 study is a double-blind, randomized, placebo-controlled Phase 3 clinical trial evaluating oral, once-a-day dosing of sabizabulin 9 mg versus placebo in

approximately 210 hospitalized moderate to severe COVID-19 patients (≥WHO 4) who were at high risk for ARDS and death. Patients were randomized in a 2:1 ratio to the sabizabulin treatment group versus placebo. Patients in both treatment groups were allowed to receive standard of care including remdesivir, dexamethasone, anti-IL6 receptor antibodies, and JAK inhibitors. The trial was conducted in the United States, Brazil, Colombia, Argentina, Mexico, and Bulgaria. COVID-19 infections treated in the study included the Delta and Omicron variants. A planned interim analysis was conducted in the first 150 patients randomized into the study. The primary efficacy endpoint was the proportion of patients that died by Day 60.

Clinical Efficacy and Safety Results
The prespecified primary endpoint was death at or before day 60. Sabizabulin treatment resulted in a clinically and statistically meaningful 55% relative reduction in deaths (p=0.0029) in the intent to treat population. Placebo group (n=52) had a 45% mortality rate compared to the sabizabulin-treated group (n=98) which had a 20% mortality rate. The secondary efficacy endpoints are still being analyzed at the time of this release.

Sabizabulin treatment was well tolerated in this patient population with no clinically relevant safety observations in the sabizabulin treated group compared to placebo.

Regulatory Discussions and Planning

The Company plans to meet with FDA to discuss next steps including the submission of an emergency use authorization application. As previously disclosed, the FDA granted Fast Track designation to the sabizabulin COVID-19 clinical program in January 2022, which the Company hopes will help streamline the emergency use authorization process.

The Company has scaled up manufacturing processes to produce commercial drug supply to address anticipated drug needs following potential FDA authorization.

The Company has been in discussions with BARDA and other US government agencies in an effort to secure an advance purchasing agreement of drug product for the U.S.

“This study represents a significant milestone in the global fight against COVID-19 as sabizabulin is the first drug to demonstrate a clinically and statistically meaningful reduction in deaths in hospitalized patients with moderate to severe COVID-19,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “We strongly believe that sabizabulin, with its dual anti-viral and anti-inflammatory properties which demonstrated positive efficacy and safety results in the Phase 3 COVID-19 study, can be that greatly needed oral therapy for hospitalized moderate to severe COVID-19 patients,” Dr. Steiner continued.

“What makes these findings more relevant is that the pharmacological activity of sabizabulin is independent of COVID-19 variant type. Pending upcoming discussion with FDA, this treatment option may be made available soon so we can be ready for when the next clinically important wave of COVID infections comes,” said Gary Barnette, PhD, Chief Scientific Officer of Veru.

“We expect new COVID-19 variant infections and new challenges in the treatment of hospitalized patients, particularly as the country heads into the fall and winter seasonal

cycle. With the results of this Phase 3 COVID-19 study, we now have a treatment option for the sickest hospitalized COVID patients," said Alan Skolnick, M.D., Principal Investigator with HD Research, who conducted this Phase 3 COVID-19 study at Memorial Hermann Memorial City Medical Center in Houston TX. "We have battled this pandemic for almost two and a half years now. A 55% reduction in deaths in hospitalized patients is tremendously meaningful to patients, their families, doctors, nurses, hospital staff and the communities they serve," added Dr. Skolnick.

Event Details
The Company will host a conference call today at 8:00 am ET to discuss the positive efficacy and safety results from the interim analysis and next steps. Interested parties may access the call by dialing 1-800-341-1602 from the U.S. or 1-412-902-6706 from outside the U.S. and asking to be joined into the Veru Inc. call. The call will also be available through a live, listen-only audio broadcast via the Internet at www.verupharma.com. Listeners are encouraged to visit the website at least 10 minutes prior to the start of the scheduled presentation to register, download and install any necessary software. 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, beginning the same day at approximately 12 p.m. (noon) ET by dialing 1-877-344-7529 for U.S. callers, or 1-412-317-0088 from outside the U.S., passcode 5820166, for one week.

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% expression (third-line metastatic setting), and which has been granted Fast Track designation by the FDA.

- Planned Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% expression (second-line metastatic setting). The Company and Eli Lilly and Company have entered into a clinical study collaboration and supply agreement for the ENABLAR-2 study. Lilly will supply Verzenio® (abemaciclib).

- Planned Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% expression (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 test to determine a patient's androgen receptor expression status and has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostic tests, which will develop and, if it is approved, commercialize the AR companion

diagnostic test.

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 study 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 to treat hot flashes in men with advanced prostate cancer undergoing androgen deprivation therapy.

In addition, sabizabulin, which has dual antiviral and anti-inflammatory effects, has completed a Phase 3 COVID-19 clinical study for the treatment of hospitalized moderate to severe COVID-19 patients (WHO 4) who were at high risk for ARDS and death. The Phase COVID-19 clinical study was stopped early for positive efficacy following a planned interim analysis. The Company is seeking an emergency use authorization.

Veru also has a commercial sexual health division - Urev, the proceeds of which help fund its drug development programs, comprised of 2 FDA approved products:

- 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 regarding: whether and when the Company will meet with FDA or receive an emergency use authorization or any approval from FDA for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization or other approval is granted; whether the Company will secure any advance purchase agreement with the U.S. government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy

Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, zuclomiphene, and ENTADFI will serve any unmet need or, what dosage, if any, might be approved for use in the US or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; 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 studies possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical studies 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 studies, 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; risks relating to the Company's development of its own dedicated direct to patient telemedicine and telepharmacy services platform, including the Company's lack of experience in developing such a platform, potential regulatory complexity, and development costs; 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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