July 6, 2022

Veru Announces New England Journal of Medicine Evidence Publication of Phase 3 Clinical Trial Results Demonstrating that Sabizabulin Treatment Significantly Reduced Deaths in High-Risk Hospitalized COVID-19 Patients

- Phase 3 Clinical Study Met Primary and Key Secondary Endpoints -

- Primary Endpoint: Sabizabulin Treatment Showed Statistically Significant and Clinically Meaningful 55.2% Reduction in Deaths Compared to Placebo in Moderate-Severe Hospitalized COVID-19 Patients -

- Key Secondary Endpoints: Sabizabulin Treatment had Significant and Clinically Meaningful Reduction in Days in ICU, Days on Mechanical Ventilation, and Days in the Hospital -

- Sabizabulin was Well Tolerated with a More Favorable Safety Profile Compared to Placebo -

- Company Submitted Request for Emergency Use Authorization to FDA on 6/7/22 -

MIAMI, July 06, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and for the management of breast and prostate cancers, today announced the publication of the results from a Phase 3 COVID-19 study evaluating the efficacy and safety of oral sabizabulin, a novel dual antiviral and anti-inflammatory agent, for the treatment of hospitalized moderate-severe COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS) and death in *The New England Journal of Medicine (NEJM) Evidence*.

The Phase 3 COVID-19 clinical trial is a double-blind, randomized, multicenter, and global placebo-controlled study evaluating oral, once-a-day dosing of sabizabulin 9 mg versus placebo in approximately 210 hospitalized moderate to severe COVID-19 patients (≥ WHO 4, supplemental oxygen) 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 treatment 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 Independent Data Safety Monitoring Committee unanimously recommended that the Phase 3 study be halted early due to clear efficacy benefit. For the primary efficacy endpoint, which was death at or before day 60, sabizabulin treatment resulted in a clinically and statistically meaningful 55.2% relative reduction in deaths (p=0.0042) in the intent to treat population (ITT). At Day 60, the placebo group (n=52) had a 45.1% mortality rate compared to the sabizabulin-treated group (n=98) which had a 20.2% mortality rate. In the overall study of 204 randomized patients, the reduction in the all-cause mortality (ITT population) was similar to the results observed in the interim efficacy analysis patient population with sabizabulin treatment resulting in a 51.6% reduction in deaths compared to the placebo group.

The key secondary endpoints included effects of sabizabulin treatment on mortality through Day 29, with a placebo mortality rate of 35.3% compared to sabizabulin treatment mortality rate of 17%, sabizabulin treatment resulted in an absolute reduction of 18.3 percentage points and a relative reduction in deaths of 51.8%. Sabizabulin treatment also resulted in a 43% relative reduction in days in ICU (p=0.0013), 49% relative reduction in days on mechanical ventilation (p=0.0013), and 26% relative reduction in days in hospital (p=0.0277) compared to placebo group. Adverse and serious adverse events were lower in the sabizabulin group compared to the placebo group.

“We are proud and honored to have the Phase 3 COVID-19 study results published in*The New England Journal of Medicine Evidence,* a highly prestigious peer reviewed medical journal. The overall conclusion of this Phase 3 study is that sabizabulin treatment has a clear mortality benefit compared to placebo in hospitalized COVID-19 patients at high risk for ARDS receiving standard of care treatment with no significant safety signals,” said Gary Barnette, PhD, Chief Scientific Officer of Veru and co-author of the *NEJM Evidence* publication.

“Unfortunately, COVID-19 is here to stay with new variants emerging and with rising rates of new cases, hospitalizations, and deaths. The current death rate from COVID-19 infection is unacceptable,” 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, co-author of the *NEJM Evidence* publication.

“We have battled this pandemic for two and a half years now, and we are still in desperate need for an effective treatment like sabizabulin to significantly reduce deaths in hospitalized COVID-19 patients. It’s in the hospital that we have the last real opportunity to prevent deaths from COVID-19 infection,” added Dr. Skolnick.

“This landmark study published in *The New England Journal of Medicine Evidence* shows the high consistency of sabizabulin treatment to significantly reduce deaths across patient subgroups regardless of standard of care treatment received, baseline WHO scores, age, comorbidities, vaccination status, COVID-19 variant, or geography,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru and co-author of the *NEJM Evidence* publication. “We have submitted a request for emergency use authorization with FDA and are in discussions with other regulatory authorities across the world.”

Regulatory Discussion and Planning

The Company submitted a request for an EUA application on June 7, 2022.

The Company has scaled up manufacturing and expects to be able to produce sufficient commercial drug supply to address anticipated drug needs following potential FDA authorization in the U.S. and subsequent authorizations in other countries and regions.

The Company is having discussions with government agencies to discuss purchases and reimbursement for sabizabulin in the U.S. and other countries around the world.

About Veru Inc.
Veru is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and ARDS-related diseases and 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.

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.

- Enrolling 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).

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.

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 receive an emergency use authorization or any approval from FDA or from any regulatory authority outside the U.S. for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients in the U.S. or anywhere outside the U.S.; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization or other approval is granted in the U.S. or in any other country; whether the Company will secure any advance purchase agreement with the U.S. government or any foreign 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 U.S. 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; and whether and when ENTADFI will be commercialized successfully. 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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