November 9, 2022

Veru Provides Update on FDA Advisory Committee Meeting Regarding Emergency Use Authorization of Sabizabulin to Treat Hospitalized COVID-19 Patients at High Risk for Acute Respiratory Distress Syndrome

MIAMI, FL, Nov. 09, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral ARDS-related diseases and for oncology, announces the results of today's meeting of the U.S. Food and Drug Administration's (FDA) Pulmonary-Allergy Drugs Advisory Committee (PADAC), which reviewed sabizabulin for Emergency Use Authorization (EUA) in hospitalized moderate to severe COVID-19 patients who are at high risk for acute respiratory distress syndrome (ARDS). The advisory committee voted 8-5 that the known and potential benefits of sabizabulin when used for the treatment of adult patients hospitalized with COVID-19 at high risk of ARDS do not outweigh the known and potential risks of sabizabulin. However, there was additional discussion around the clinical trial design aspects of an additional clinical trial as a potential post authorization requirement. FDA will consider the input of the advisory committee as part of their review of the EUA and render a decision on the Emergency Use Authorization.

"We look forward to continuing to work with the FDA as we continue our efforts to ensure that this product is available to patients in a timely manner," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru.

"In a still evolving COVID-19 pandemic taking the lives of over 300 U.S. citizens a day and with the threat of new virus variants looming that may not be as easily treated with the limited array of presently used therapies, there is an urgent need for newer therapies with much greater effectiveness than what is available. Sabizabulin with its unique action as a microtubular disruptor, both reducing inflammation and viral replication independent of virus variant, shows compelling promise," said Erik Swenson, M.D. Professor of Medicine, Physiology, and Biophysics, University of Washington, and former Chairman of PADAC. "In a recently published well-executed double-blind placebo-controlled trial of patients with respiratory compromise and at high risk of developing ARDS, sabizabulin reduced absolute mortality at 60 days by 20.5%, compared to 0-6% for all other available drugs. In the long history of drug trials for patients with severe respiratory failure over many decades, there has

never been a drug to show such dramatic protection."

"Adding sabizabulin to the cadre of therapies among hospitalized patients with COVID-19 is crucial in the effort to reduce mortality among a group of patients who have seen the least reduction in death despite newer treatments and approaches," said Christian Sandrock, M.D. Division Vice Chief of Internal Medicine and Director of Critical Care University of California, Davis, School of Medicine.

Phase 3 sabizabulin clinical study:

A double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial was conducted in 204 hospitalized COVID-19 patients with moderate to severe COVID-19 at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Based on a planned interim analysis of the first 150 patients randomized, the Independent Data Monitoring Committee unanimously halted the study for clear clinical efficacy and no safety concerns were identified. Treatment with sabizabulin 9 mg once daily, an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory and antiviral properties, resulted in a clinically meaningful and statistically significant 55.2% relative reduction in deaths compared to placebo. In the full study, there were 204 patients enrolled, and for the primary endpoint, there was a clinically meaningful and statistically significant 20.5% absolute reduction and 51.6% relative reduction in mortality at Day 60. In June, the Company submitted a request for Emergency Use Authorization to FDA. On July 6, 2022, the Company announced the publication of the Phase 3 COVID-19 trial results evaluating the efficacy and safety of oral sabizabulin in The New England Journal of Medicine Evidence®.

Global regulatory activities:

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) informed the Company on July 25, 2022, that the sabizabulin marketing authorization application will receive expedited review. On July 27, 2022, The European Medicines Agency's Emergency Task Force initiated the review of sabizabulin treatment for hospitalized COVID-19 patients for emergency use in European Union countries. On August 22, 2022, Australia's Therapeutic Goods Administration (TGA) determined that sabizabulin treatment in hospitalized COVID-19 patients at high risk for ARDS qualifies for an expedited, provisional registration regulatory pathway.

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

In addition to COVID-19 infectious disease program, the company has:

Oncology program:

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 is supplying 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.

Commercial sexual health program, Urev, has 2 FDA approved products:

- ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia.

- 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; the extent of any conditions imposed on any potential emergency use authorization for sabizabulin; the timing of any FDA decision on the emergency use authorization for sabizabulin; 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 phase 3 clinical trial results for sabizabulin

will be repeated in a clinical setting; 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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