June 1, 2023

Veru Announces Appointment of Dr. Erik Swenson and Dr. Robert Schooley to its Infectious Disease Scientific Advisory Board

MIAMI, FL, June 01, 2023 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-CoV-2 and other viral ARDS-related diseases, today announced the appointment of Erik Swenson, M.D., a world-renowned pulmonologist specializing in critical care, and Robert Schooley, M.D., an accomplished infectious disease physician and researcher, to its Infectious Disease Scientific Advisory Board (SAB) to join David D. Ho, M.D., a trailblazer of infectious disease viral research and therapeutic development, who is Chairman of the SAB.

“We are pleased to share that Dr. Erik Swenson and Dr. Robert Schooley are joining our Scientific Advisory Board focused on infectious diseases,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “Our Company’s strategy to progress sabizabulin for serious and life-threatening infectious diseases like viral induced ARDS is consistent with both doctors’ pertinent and extensive experiences and professional aims. We are fortunate to receive their scientific guidance and support, alongside Dr. David Ho’s, to continue advancing sabizabulin, an important, potentially lifesaving drug candidate.”

Erik Swenson, M.D. is a pulmonologist affiliated with Veterans Affairs Puget Sound Health Care System-Seattle. Dr. Swenson specializes in critical care medicine, internal medicine and pulmonology, with particular concentration in adult acute respiratory distress syndrome (ARDS), pulmonary hypertension, chronic obstructive pulmonary disease, asthma, and tuberculosis for over four decades. Additionally, he is a Professor of Medicine, Physiology and Biophysics at the University of Washington and previously served as the Chairman of the U.S. FDA’s Pulmonary-Allergy Drugs Advisory Committee for 10 years. Dr. Swenson received his M.D. from University of California San Diego School of Medicine.

“I am grateful for the opportunity to work closely with Veru’s experienced scientists and executives who are working diligently to deliver a novel medicine with antiviral and anti-inflammatory properties to patients suffering from viral induced ARDS,” said Erik Swenson, M.D.

Robert Schooley, M.D., an infectious disease specialist, is affiliated with UC San Diego Health-La Jolla and Hillcrest, where he serves as a Professor in the Division of Infectious

Diseases at UC San Diego School of Medicine. His primary research interests include influenza, global health and international medicine, and the diagnosis and management of infections that cause death and morbidity in resource-limited settings. Notably, Dr. Schooley played a key role as one of the first researchers to describe the humoral and cellular immune responses to HIV infection. He received his M.D. from Johns Hopkins University School of Medicine.

“The clinical data Veru has generated in COVID-19 induced ARDS and more recently preclinically in smallpox and influenza, additional viral ARDS-related diseases, indicate the Company is poised to potentially provide a therapeutic solution to patients worldwide. I am excited to serve as a member of its Scientific Advisory Board during this major inflection point,” said Robert Schooley, M.D.

Drs. Swenson and Schooley join David D. Ho, M.D., Chairman of Veru’s SAB. David D. Ho, M.D. is the Founding Scientific Director of the Aaron Diamond AIDS Research Center and the Clyde and Helen Wu Professor of Medicine at Columbia University Irving Medical Center, a Member of The National Academy of Medicine, Member of The American Academy of Arts & Sciences, and a Fellow of The American Association for the Advancement of Science. He received his M.D. from Harvard Medical School and has received fourteen honorary doctorates over the course of his career. In his noteworthy research, Dr. Ho discovered the nature of HIV replication, and the resulting innovative combination therapy remarkably enabled patients to manage this disease. In 1996, Dr. Ho was selected by TIME Magazine as man of the year as a doctor who gives hope to millions in the daunting fight against HIV. In addition, Dr. Ho is leading a multi-disciplinary team of physicians, and scientists to advance the development of new drugs that target SARS-CoV-2 mutants.

About Veru Inc.
Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-CoV-2 and other viral ARDS-related diseases.

Oncology program focuses on breast cancer

The Company’s late stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist.

- Enrolling Phase 2b/3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) combination in AR+ ER+ HER2- metastatic breast cancer (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/3 study of enobosarm in nonmeasurable bone only metastatic breast cancer.

Infectious disease program focuses on viruses that pose serious worldwide global threat

- **COVID-19:** Sabizabulin is an oral, first-in-class, new chemical entity, microtubule

disruptor that has dual anti-inflammatory and host mediated antiviral properties. Veru has conducted a positive double-blind, randomized, placebo-controlled Phase 3 COVID-19 clinical trial in 204 hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death. The primary endpoint was the proportion of deaths by Day 60. Treatment with sabizabulin resulted in a clinically meaningful and statistically significant 51.6% relative reduction in deaths (p=0.0046) and was well tolerated. FDA granted Fast Track designation to the Company's COVID-19 program in January 2022. In April 2023, the Company reached agreement with FDA on design of Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS. The Company plans to initiate this Phase 3 clinical study in 2H 2023.

- **Smallpox and Ebola viruses:** The Company is planning a pre-IND meeting with FDA to discuss the development of sabizabulin for smallpox virus and Ebola virus under the Animal Rule FDA regulatory approval pathway.

- **Influenza:** The Company is planning a Phase 3 clinical trial to evaluate sabizabulin in hospitalized influenza patients at high risk for ARDS.

Sexual health program – Urev

Veru has a commercial sexual health division called Urev that is comprised of:

- 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: the planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company's current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 2b/3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 2b/3 study of enobosarm in bone-only non-measurable hormone receptor and HER2- metastatic breast cancer, the Phase 3 study of sabizabulin in hospitalized influenza patients at high risk of ARDS, and studies of sabizabulin in smallpox virus and Ebola virus, and whether any of such studies will meet any of its primary or secondary endpoint; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients will occur and what the results of any such interim analyses will be; whether the results of such interim analyses or the completed confirmatory Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA; whether and when any potential EUA or NDA would be grated; whether and when the Company will meet with BARDA regarding any potential partnering opportunities and whether those efforts will be successful; whether and how the Company will fund the planned Phase 3 studies of sabizabulin in influenza, pox virus and COVID-19; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether the current and future clinical development efforts of the Company, including all studies of sabizabulin in infectious disease indications and

enobosarm in oncology indications, and any of their results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of any of the Company's drug candidates; whether the drug candidates will be approved for the targeted line of therapy; whether sabizabulin will become a treatment for broad ARDS; whether the Company's FC2 telemedicine portal sales will grow or replace prior revenue from the U.S. prescription sales of FC2; whether the Company will recover any of the monies owed it by The Pill Club; whether and when the Company will receive the remaining installments from Blue Water in connection with the sale of ENTADFI or will receive any of the potential sales milestones related thereto; whether, when and how many shares may be sold under the Lincoln Park Capital Fund equity line; and whether the Company's current cash will be sufficient to fund its planned or expected operations. 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 as well as other operations of the Company; the timing of any submission to the FDA or any other regulatory authority and any determinations made by the FDA or any other regulatory authority; the possibility that as vaccines, anti-virals and other treatments 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, including FC2 and ENTADFI and, if authorized, sabizabulin, 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; 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 and securities litigation; 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, 2022 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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