May 4, 2023

Veru Reaches Agreement with FDA on Confirmatory Phase 3 Clinical Trial for Sabizabulin Treatment of Hospitalized COVID-19 Adult Patients at High Risk for ARDS

Reached agreement with FDA on confirmatory Phase 3 clinical trial design in 408 subjects with primary endpoint of all-cause mortality at Day 60

Study to expand treatment population to include all WHO-4, WHO-5, and WHO-6 hospitalized adult COVID-19 patients at high risk for ARDS regardless of the presence of comorbidities

Two interim efficacy analyses are planned; study may be stopped if statistical criteria are met for efficacy

If confirmatory Phase 3 clinical trial meets statistical significance, Veru may consider submission of a new request for EUA and/or NDA

Enrollment is expected to initiate in the second half of 2023 and the first planned interim efficacy analysis expected in 2024

MIAMI, FL, May 04, 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 that in an April 27, 2023 meeting, the Company and FDA reached agreement on the design of the Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin treatment in hospitalized moderate to severe COVID-19 patients who are at high risk for acute respiratory distress syndrome (ARDS) and the path forward to submit a new Emergency Use Authorization (EUA) application and/or New Drug Application (NDA). Based on the FDA's positive feedback on the confirmatory Phase 3 clinical study design and program, the Company anticipates initiating the clinical study in the second half of 2023.

Highlights from the April 27th FDA meeting

FDA agreed to a confirmatory Phase 3, randomized (1:1), multicenter, global, efficacy and safety study of sabizabulin 9mg oral daily dose plus standard of care treatment versus placebo plus standard of care treatment in 408 hospitalized adult patients with moderate to

severe SARS-CoV-2 infection who are at high risk for ARDS:

- Indication (patient population) for sabizabulin has been expanded to include all hospitalized moderate to severe COVID-19 patients: WHO-4 (passive, low flow oxygen), WHO-5 (forced, high flow oxygen), or WHO-6 (mechanical ventilation) without a requirement to have a comorbidity.

- Endpoints:
  - Primary efficacy endpoint is all-cause mortality at Day 60
  - Secondary endpoints include Days in the hospital, Days in the ICU, Days on mechanical ventilation, and proportion of patients alive without respiratory failure
  - Exploratory endpoint is the presence of long COVID-19 symptoms at Day 180

- In order to get a potentially efficacious drug to patients in an efficient time frame, two interim efficacy analyses are planned: the first planned interim analysis is expected to occur when 50% of patients (204) have completed the Day 60 primary efficacy endpoint as recommended by FDA, and the second planned interim analysis is expected to occur when 71% of patients (290) have completed the Day 60 primary efficacy endpoint. If either planned interim efficacy analysis meets statistical significance criteria, the trial could be stopped.

- Should the pre-specified primary efficacy endpoint analysis demonstrate a statistically significant effect on all-cause mortality favoring sabizabulin – the Company may consider a new request for an EUA and/or a submission of an NDA, as the Company would have two adequate and well controlled trials demonstrating efficacy.

- As the program has FDA Fast Track designation, a rolling NDA submission is a possibility for sabizabulin.

The Phase 3 confirmatory COVID-19 clinical trial is expected to begin enrolling in the second half of 2023, and the first planned interim efficacy analysis is anticipated to be conducted in 2024.

"While we remain confident that the efficacy and safety data already generated on sabizabulin for the treatment of hospitalized patients with moderate to severe COVID-19 infection qualifies for an emergency use authorization, it is important to continue the development toward full approval and obtaining regulatory clarity on the design of our confirmatory Phase 3 clinical study and a path forward for a new EUA and/or NDA submission is the important first step," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. "We look forward to expanding the clinical development of sabizabulin into a broader group of hospitalized patients at high risk for ARDS. ARDS is the leading cause of COVID-19 related deaths. Endemic COVID-19 infections still result in an unacceptably high death rate of 4,500 U.S. deaths a month and average of 4,200 hospitalizations a day in spite of vaccines and current standard of care treatments. Furthermore, a new highly contagious COVID-19 strain, Arcturus, has emerged and is being carefully monitored. As for other viral causes of ARDS, we recently shared in preclinical studies that sabizabulin had efficacy in ARDS caused by influenza H1N1 and demonstrated antiviral activity against Vaccinia pox virus. We believe sabizabulin could emerge as the leading treatment option for hospitalized patients at high risk for viral associated ARDS

broadly."

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. The Company is planning to conduct a Phase 3 confirmatory clinical trial to evaluate sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS.
- **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 Rules 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 and scope of the planned confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients; whether the confirmatory Phase 3 study will meet any of its primary or secondary endpoints and whether any of its exploratory endpoints will yield useful data; whether and when any of the planned interim analyses in this new Phase 3 study will occur and what the results of any such interim analyses will be; whether the results of the interim analyses or the completed 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 the Company’s clinical programs for enobosarm or sabizabulin will yield Phase 3 clinical trial data in 2024; 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 telemedicine customers for FC2 will return to historical ordering patterns or increase their purchases of FC2 at all; 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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