April 4, 2023

Veru Announces Preclinical Results from Expanded Sabizabulin Program into Influenza-Induced Severe Acute Respiratory Distress Syndrome and Provides Update on COVID-19 Program

In the final report, sabizabulin significantly reduced key cytokines involved in Acute Respiratory Distress Syndrome (ARDS) in H1N1 influenza pulmonary inflammation murine ARDS model

Positive Phase 3 COVID-19 clinical study and preclinical influenza study further support the potential use of sabizabulin as a broad antiviral and anti-inflammatory agent for viral-induced ARDS

- **Expedited meeting granted by U.S. FDA in April 2023 for Phase 3 confirmatory study in hospitalized COVID-19 patients at high risk for ARDS**
- **Veru plans Phase 3 clinical study in hospitalized influenza patients at high risk for ARDS**

MIAMI, FL, April 04, 2023 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), Veru Inc., a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral ARDS-related diseases and for oncology, today announced results from a preclinical study of sabizabulin demonstrating robust anti-inflammatory activity with improved outcomes in an Influenza-Induced Pulmonary Inflammation Mouse Acute Respiratory Distress Syndrome (ARDS) Model.

Preclinical study background:

An animal study was conducted by a team of researchers at Labcorp Early Development Laboratories, Ltd, United Kingdom. The purpose of the study was to evaluate the efficacy of sabizabulin in the influenza H1N1 pulmonary inflammation mouse ARDS model. Two hours before starting treatment, mice were administered H1N1 or saline via the intranasal route to induce a viral infection and inflammatory response in the lung followed by daily treatments with saline, sabizabulin, dexamethasone (anti-inflammatory control), or oseltamivir (direct antiviral control).

Clinical signs and longitudinal lung function (Penh) were measured, bronchioalveolar lavage

(BAL), which is washings from lungs, was collected to determine both amounts of inflammatory cells and levels of cytokines, and histopathologic examination of lungs was performed to evaluate inflammation.

Preclinical study results highlights:

Sabizabulin treatment resulted in a statistically significant decrease in the total number of inflammatory cells (-53%) ($p<0.01$) in BAL fluid, including statistically significant reductions in both the innate and adaptive immune cells. In addition, sabizabulin treatment showed a statistically significant reduction in key cytokines and chemokines in BAL fluid that are part of the cytokine storm responsible for the acute lung injury: Keratinocyte-derived chemokine (KC) (-38%;$p<0.01$), Interleukin-6 (IL-6) (-74%;$p<0.001$), TNF-α (-36%;$p<0.05$), Interferon-γ (INF-γ) (-84%;$p<0.001$), and CXCL-10 (-60%;$p<0.001$). In contrast, dexamethasone treatment did not demonstrate a statistically significant reduction in the total number of inflammatory cells in the BAL fluid. Dexamethasone also had a different effect from sabizabulin on cytokine production in the BAL fluid. Dexamethasone treatment resulted in statistically significant reductions for IL-6 (-52 %;$p<0.01$) and INF-γ (-81 %;$p<0.001$), but no statistically significant changes for KC (+20%), TNF-α (-13%), and CXCL- 10 (-8%).

Clinically, sabizabulin treatment resulted in a reduction in the severity of lung inflammation (by histopathology) and a dose-dependent improvement of lung function (lower Penh vs untreated H1N1 infection). Oral administration of 2 mg/kg sabizabulin resulted in the reduction of the clinical signs and body weight loss associated with H1N1 infection. From Day 11, four out of seven animals displayed no clinical signs associated with the induction of H1N1 infection. Whereas, oral administration of 1 mg/kg dexamethasone did not result in reduction of the clinical signs or body weight loss associated with H1N1 infection.

The Company expects to submit the full data set for presentation in future scientific meetings and peer-reviewed publications.

Sabizabulin’s anti-inflammatory effects were previously reported in a preclinical septic shock mouse model with suppression of key cytokines responsible for severe acute respiratory distress syndrome (ARDS). This mouse model predicted the clinical benefit of sabizabulin demonstrated in a positive randomized, multicenter placebo-controlled Phase 3 clinical trial in hospitalized moderate to severe COVID-19 patients who were at high risk for ARDS and death. Sabizabulin treatment plus standard of care resulted in a 51.6% relative reduction in deaths compared to placebo plus standard of care (odds ratio, 2.77; 95% CI confidence interval, 1.37 to 5.60; $p=0.0046$).

These data suggest that sabizabulin has the potential to be an effective treatment for hospitalized influenza patients at high risk for ARDS and death. Pathogenesis and mortality rates for patients with hospitalized influenza ARDS are similar to COVID-19-associated ARDS, representing a high unmet need with very limited treatment options. According to CDC, the influenza burden estimates in the United States were up to 630,000 hospitalizations and up to 55,000 deaths in the past 6 months. Accordingly, Veru is planning a double-blind randomized placebo-controlled Phase 3 clinical trial evaluating sabizabulin in hospitalized adult influenza patients at high risk for ARDS.

“Viral-induced acute respiratory distress syndrome is a leading cause of death in patients with COVID-19 and influenza and remains an unmet medical need worldwide,” said Mitchell

Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “Sabizabulin, as a host targeted antiviral and broad spectrum anti-inflammatory agent, has the potential to address the two most common causes of viral-induced ARDS: COVID-19 and influenza. Based on the preclinical data highlighted today, we plan to initiate a Phase 3 study of sabizabulin in influenza patients at high risk for ARDS, as well as expand the sabizabulin program into other serious virus infections that result in ARDS and potentially death. Furthermore, we look forward to providing an update on the upcoming FDA meeting we will be having this month to finalize the clinical trial design for the Phase 3 confirmatory COVID-19 study and to confirm the requirements for an EUA submission and new drug application.”

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 treatment of breast cancer.

Infectious disease program

- **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. Veru has been granted a meeting with U.S. FDA in April 2023 to finalize clinical trial design and requirements for an EUA submission and new drug application.

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

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

- Enrolling Phase 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 3 study of enobosarm in nonmeasurable bone only metastatic breast cancer.

Sexual health program - Urev
Veru also has a commercial sexual health division - Urev - 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 the preclinical results of sabizabulin reported here will be replicated sufficiently or at all in a planned Phase 3 study; whether and when the Company will commence the Phase 3 influenza study and the confirmatory COVID-19 study for sabizabulin; whether and when the planned Type C meeting with the FDA regarding the confirmatory Phase 3 sabizabulin study will happen as planned, what the resulting protocol for such study might be and when the Company will disclose any such protocol publicly; whether and how the Company will fund the planned Phase 3 studies of sabizabulin in influenza and COVID-19; whether and when the Company will submit the full data set for the preclinical study announced here for presentation in future scientific meetings and peer-reviewed publications and whether and when such full data set will be accepted by any such meetings or publications; 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 ENTADFI will be commercialized successfully, the Company will grow sales of ENTADFI or the Company will be able to successful partner with any other entity to grow sales of ENTADFI; 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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