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Veru Announces Preclinical Study Results that Demonstrate Sabizabulin Inhibits Poxviruses

Sabizabulin inhibited the cell release and cell-to-cell spread of poxvirus in a preclinical study

Veru further expands study of sabizabulin for the treatment of poxvirus acute respiratory distress syndrome (ARDS)

Company plans pre-Investigational New Drug (IND) meeting with FDA to evaluate sabizabulin under the Animal Rule regulatory pathway for treatment of smallpox virus outbreak

MIAMI, FL, April 11, 2023 (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, today announced results from a preclinical *in vitro* study evaluating the effects of sabizabulin against prototypical poxvirus, vaccinia virus, which demonstrated that sabizabulin prevented both the release of poxvirus from infected cells and the spread of poxvirus to healthy cells. These preclinical study results support the expansion of sabizabulin's program into additional indications to potentially treat the lethal smallpox virus infection or other related infections if a worldwide emergency outbreak occurs.

Preclinical study background:

The study was conducted by a team of researchers led by Brian M. Ward, Ph.D., Associate Professor of Microbiology and Immunology, University of Rochester School of Medicine and Dentistry, Rochester, New York. The purpose of the study was to evaluate the mechanism of antiviral efficacy of sabizabulin, a novel microtubule disruptor, against the prototypical poxvirus vaccinia in cell culture. Vaccinia virus uses the host cell's microtubules for intracellular transport to reproduce, and to release newly formed infectious viral particles out of the cell called extracellular enveloped virus (EEV) which then spread to healthy cells to cause widespread virus infection.

Preclinical study results highlights:

Treatment of BSC40 cells (African green monkey kidney cells) with different concentrations of sabizabulin before inoculation with vaccinia virus demonstrated a drug dose-dependent inhibition of infectious extracellular enveloped virus (EEV) release (R2 value=0.9573) with an

inhibition concentration of 50% and 90% of 24.3nM and 37.8nM concentrations of sabizabulin, respectively. To assess the ability of sabizabulin to slow or stop vaccinia virus cell-to-cell spread, BSC40 cells were treated with different concentrations of sabizabulin before inoculation with vaccinia virus at a low multiplicity of infection. A clear drug dose-dependent inhibition of cell-to-cell spread of vaccinia virus was observed (R2=0.9464) with an inhibition concentration of 50% and 90% at 15.7nM and 27nM concentrations of sabizabulin, respectively.

The concentrations of sabizabulin required to inhibit vaccinia virus release from infected cells and to stop cell-to-cell spread may be achieved at the 9mg daily oral dose of sabizabulin as patients treated at this dose have an average blood concentration (C_{avg}) of about 32nM sabizabulin and peak concentration levels (C_{max}) of 171nM sabizabulin.

In this study, sabizabulin, by disrupting microtubules, was able to prevent the export and release of infectious vaccinia virus. These findings are consistent with sabizabulin's mechanism of action as a host targeted antiviral as it targets a component of the cell, microtubules, that viruses use to cause infection.

Sabizabulin, as a host targeted antiviral and broad anti-inflammatory agent, may be useful as a novel treatment not only against smallpox and other poxviruses, but also may reduce the hyperactive immune response triggered by poxviruses that is responsible for severe pneumonia, ARDS, multi-organ failure, and death.

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

"The results are very encouraging," said Brian M. Ward Ph.D. Associate Professor of Microbiology and Immunology who conducted the research at the University of Rochester Medical Center. "We have known for a long time that orthopoxviruses such as Vaccinia, Monkeypox, and Variola (the causative agent of smallpox) depend on the cell's microtubule network for egress, virus release, and ultimately cell-to-cell spread. Sabizabulin targets this network and appears to be very effective at preventing virus spread *in vitro*."

"Any smallpox, Ebola, or Marburg virus outbreak would be an immediate global emergency with limited existing options available for treatment," 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 virus release and the resulting cytokine storm that causes ARDS, multi-organ failure, and death. Based on the preclinical data highlighted today, we expect to expand the sabizabulin program to include other serious virus infections that pose a global public health threat to society. We plan to meet with FDA to develop a clinical plan under the Animal Efficacy Rule regulatory pathway to develop and to approve sabizabulin for smallpox virus. We are also planning to meet with U.S.' Biomedical Advanced Research and Development Authority (BARDA) next month to assess contract and partnership opportunities."

FDA's "Animal Rule" regulatory approval pathway

The Company plans to have a pre-IND meeting with the FDA to discuss Animal Rule regulatory requirements for assessing the efficacy of sabizabulin for poxvirus as well as Ebola and Marburg viruses. Clinical human efficacy trials of drugs for preventing or treating smallpox, Ebola, and Marburg viruses are not feasible and challenge studies in healthy

subjects are unethical. Therefore, drugs for these indications are developed and approved under a regulatory pathway commonly referred to as the *Animal Rule* (21 CFR part 314, subpart I, for drugs and 21 CFR part 601, subpart H, for biologics). FDA may grant marketing approval based on adequate and well-controlled animal efficacy studies when the results of those studies establish that the drug is reasonably likely to produce clinical benefit in humans.

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 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. 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.
- **Smallpox, Ebola, and Marburg viruses:** The Company is planning a pre-IND meeting with FDA to discuss the development of sabizabulin for smallpox virus, Ebola, and Marburg 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.

Oncology program focus on breast cancer

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 or earlier in influenza will be replicated sufficiently or at all in a planned Phase 3 study; whether the FDA will agree with the Company’s planned regulatory pathway; the expected timing of any such further development of sabizabulin, the potential size and geographic scope of any potential market and whether any outbreaks that could potentially be treated with sabizabulin will occur; whether and when the Company will commence the Phase 3 influenza study, any poxvirus 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 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 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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