April 27, 2023

Veru to Report Fiscal 2023 Second Quarter Financial Results on May 11, 2023

MIAMI, FL, April 27, 2023 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a biopharmaceutical company focused on developing novel medicines for oncology and SARS-CoV-2 and other viral ARDS-related diseases, today announced it will host a conference call and audio webcast on Thursday, May 11, 2023, at 8:00 a.m. ET to discuss its fiscal 2023 second quarter financial results and provide a business update.

The audio webcast will be accessible under “Investor Kit” in the Investors page of the Company’s website at www.verupharma.com. To join the conference call via telephone, please dial 1-800-341-1602 (domestic) or 1-412-902-6706 (international) and ask to join the Veru Inc. call. An archived version of the audio webcast will be available for replay on the Company’s website for approximately three months. A telephonic replay will be available on May 11, 2023 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 1592419, for one week.

About Veru Inc.
Veru is a 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 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.

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.

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 Company's current and planned clinical trial programs, the timing, design and enrollment of any such trials and whether and when any such trials will read out data or meet any primary or secondary endpoints, including phase 3 trials for sabizabulin for certain COVID patients and for certain ARDS patients and phase 3 trials for enobosarm in certain breast cancers; 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 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; 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 FC2 product 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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