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Veru to Report Fiscal 2023 First Quarter Financial Results on February 9, 2023

MIAMI, FL, Jan. 26, 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 it will host a conference call and audio webcast on Thursday, February 9, 2023, at 8:00 a.m. ET to discuss its fiscal 2023 first 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 An archived version of the audio webcast will be available for replay on the Company’s website for approximately three months.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 February 9, 2023 at approximately 12:00 p.m. ET by dialing 1-877-344-7529 (domestic) or 1-412-317-0088 (international), passcode 9127050, for one week.

About Veru Inc.
Veru is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral ARDS-related diseases and for oncology. The Company’s infectious disease development program includes sabizabulin, an oral microtubule disruptor, for the treatment of hospitalized moderate to severe COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS). In the final analysis of the Phase 3 trial, treatment with sabizabulin 9 mg once daily resulted in a clinically meaningful and statistically significant 51.6% relative reduction in deaths compared to placebo. Sabizabulin for COVID-19 is currently under regulatory review for potential emergency or conditional authorization by U.S. FDA, European Union’s EMA, United Kingdom’s MHRA, Australia’s TGA, Canada’s Health Canada, South Korea’s MFDS, and Switzerland’s Swissmedic.

The Company’s breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin. Veru’s oncology program also includes product candidates in development for the treatment of prostate cancer: sabizabulin, VERU-100, a long-acting GnRH antagonist and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

The Company’s commercial sexual health program, Urev, has 2 FDA approved products, including ENTADFI™ (tadalafil and finasteride) capsules for oral use, a new treatment for benign prostatic hyperplasia and 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 Company will successfully develop or commercialize any drug in the infectious disease area and whether any such drug will serve a potentially life-saving unmet need; whether the Company's infections disease franchise will generate any commercially available product and whether it will expand sabizabulin or any other compound beyond the potential treatment of certain COVID-19 patients; whether the Scientific Advisory Board will successfully make a meaningful contribution to sabizabulin's prospects or Veru's prospects or plans generally; whether any other leading physicians or scientists will join Veru's Scientific Advisory Board; whether and when the Company will receive an emergency use authorization or any approval from FDA or from any regulatory authority outside the U.S. for sabizabulin for certain COVID-19 patients; whether and when sabizabulin will become an available treatment option for certain COVID-19 patients in the U.S. or anywhere outside the U.S.; whether any additional efficacy or safety clinical studies of sabizabulin for certain COVID-19 patients will be required by the FDA or any other regulatory authority as a condition to any authorization or as a post-authorization requirement; whether the Company will have sufficient supply of sabizabulin to meet demand, if an emergency use authorization or other approval is granted in the U.S. or in any other country; whether the Company will secure any advance purchase agreement with the U.S. government or any foreign government; whether the current and future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates and companion diagnostic; whether the drug candidates will be approved for the targeted line of therapy; the anticipated design and scope of clinical studies and FDA acceptance of such design and scope; whether any regulatory pathways, including the accelerated Fast Track designations, to seek FDA approval for sabizabulin, enobosarm or any of the Company's drug candidates are or continue to be available; whether the expected commencement and timing of the Company's clinical studies, including the Phase 3 ENABLAR-2 study, the sabizabulin monotherapy Phase 2b clinical study for 3rd line treatment of metastatic breast cancer, the Phase 2 registration clinical study for VERU-100, and the development of the companion diagnostic will be met; when clinical results from the ongoing clinical studies will be available, whether sabizabulin, enobosarm, VERU-100, or zuclomiphene will serve any unmet need or, what dosage, if any, might be approved for use in the U.S. or elsewhere, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, and the timing of the Company's submissions to FDA and FDA's review of all such submissions; whether any of the selective clinical properties previously observed in clinical studies of sabizabulin, enobosarm, VERU-100 or other drug candidates will be replicated in the current and planned clinical development program for such drug candidates and whether any such properties will be recognized by the FDA in any potential approvals and labeling; whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use; 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, especially if any authorizations for sabizabulin for certain COVID-19 patients are not obtained. 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; 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 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; the Company's ability to successfully commercialize any of its products, if approved; 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; 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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