

January 26, 2022



Veru to Report Fiscal 2022 First-Quarter Financial Results, Host Conference Call on February 9th

MIAMI, Jan. 26, 2022 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of breast and prostate cancer, today announced that it will report financial results for its fiscal 2022 first quarter, on Wednesday, February 9, 2022, before the market opens. Veru's management will host a conference call that same day at 8 a.m. ET to review the Company's performance and to answer questions. The call will also be accessible via webcast.

Event Details

Interested parties may access the call by dialing 1-800-341-1602 from the U.S. or 1-412-902-6706 from outside the U.S. and asking to be joined into the Veru Inc. call. The call will also be available through a live, listen-only audio broadcast via the Internet at www.verupharma.com. Listeners are encouraged to visit the website at least 10 minutes prior to the start of the scheduled presentation to register, download and install any necessary software. A playback of the call will be archived and accessible on the same website for at least three months. A telephonic replay of the conference call will be available, beginning the same day at approximately 12 p.m. (noon) ET by dialing 1-877-344-7529 for U.S. callers, or 1-412-317-0088 from outside the U.S., passcode 3664461, for one week.

About Veru Inc.

Veru is an oncology biopharmaceutical company with a principal focus on developing novel medicines for the management of breast and prostate cancers.

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor.

Current studies on the two drugs include:

- Enrolling Phase 3 ARTEST study of enobosarm in androgen receptor positive, estrogen receptor positive, and human epidermal growth factor receptor two negative (AR+ ER+ HER2-) metastatic breast cancer with AR \geq 40% (third-line metastatic setting), and which has been granted Fast Track designation by the U.S. Food and Drug Administration
- Planned Q1 2022 Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6

inhibitor) in AR+ ER+ HER2- metastatic breast cancer with AR \geq 40% (second-line metastatic setting)

- Planned Q1 2022 Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% (third-line metastatic setting)

The Company has determined that patients who have \geq 40% androgen receptor nuclei staining by immunohistochemistry in their breast cancer tissue, a measure of AR expression, are most likely to respond to enobosarm. Consequently, Veru is developing a companion diagnostic to determine a patient's androgen receptor expression status, and has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostics, which will develop and, if it is approved, commercialize the companion AR diagnostic.

Veru's late-stage prostate cancer portfolio comprises sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist.

Current studies on these drugs include:

- Enrolling Phase 3 VERACITY and ongoing Phase 2 studies of sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy
- Enrolling Phase 2 dose-finding study of VERU-100 in advanced hormone-sensitive prostate cancer
- Planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer undergoing androgen deprivation therapy who suffer from hot flashes

In addition, sabizabulin, which has dual antiviral and anti-inflammatory effects, is currently enrolling in a Phase 3 study for the treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome, also known as the cytokine storm.

Veru also has a commercial sexual health division, the proceeds of which help fund its drug development programs, comprised of:

- 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 Company's current or future clinical development program results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates; whether the expected timelines for any of the Company's clinical trials will be met; whether the companion diagnostic for enobosarm will be developed successfully or be approved by

the FDA for use; and when commercial launch of ENTADFI will occur. 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 trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials 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 and any determinations made by the FDA or any other regulatory authority; the actions of any of our collaboration partners; 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 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 trials, 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; 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, 2021 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.

Investor and Media Contact:

Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com



Source: Veru Inc.