

June 21, 2023



Veru Inc.'s Oncology Drug Research Program Partner, The University of Tennessee Health Science Center, Awarded Two New Federal Grants

Research grants from U.S. Department of Defense (DoD) and National Cancer Institute's Research Project Grant (NCI R01) awarded to UTHSC to study new types of targeting agents for multiple cancer indications with significant unmet need

Aggregate funding for UTHSC exceeds \$10M for these oncology drug research programs

Veru has rights to further develop and commercialize potential oncology agents generated from this research

MIAMI, FL, June 21, 2023 (GLOBE NEWSWIRE) -- The University of Tennessee Health Science Center (UTHSC), oncology drug discovery research partner to Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing novel medicines for the treatment of breast cancer and for SARS-CoV-2 and other viral ARDS-related diseases, has secured two additional grants to develop oncology therapeutics for indications of high unmet need. UTHSC was awarded \$924,000 from the U.S. Department of Defense (DoD) and \$3,074,470 from the National Cancer Institute's Research Project Grant (NCI R01). These two new grants awarded to UTHSC bring the university's aggregate oncology funding related to this project to over \$10 million.

Through the Company's collaboration with UTHSC, leveraging its existing sponsored research agreement and its private-public partnership and other arrangements with UTHSC, Veru holds the opportunity to continue to develop and to potentially commercialize oncology agents developed by this research which include:

- Targeting drugs, including conjugated drugs for metastatic prostate cancer and for drug-resistant hormone receptor positive HER2- metastatic breast cancer as well as brain and bone metastases from breast cancer
- Novel targeting drugs for drug resistant advanced ovarian cancer

The research conducted at UTHSC is led by Dr. Wei Li, Ph.D., Principal Investigator and Distinguished Professor of Pharmaceutical Sciences and Director of the Drug Discovery Center in the College of Pharmacy, and includes Dr. Duane D. Miller, Ph.D., Professor Emeritus of Pharmaceutical Sciences, Dr. Tiffany N. Seagroves, Ph.D., Professor of Pathology in the College of Medicine, and Dr. Junming Yue, Ph.D., associate professor of

Pathology in the College of Medicine.

“We are pleased with our longstanding research collaboration with the University of Tennessee Health Science Center investigating new compounds for oncology, which has garnered additional DoD and NCI funding for new research projects,” said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. “Dr. Wei Li and Dr. Duane Miller’s research labs have demonstrated a track record of discovering important agents in advanced cancers. Furthermore, we are particularly excited about the expansion of their research into targeting cancer using drug conjugates, which may increase efficacy of these drugs with fewer unwanted side effects. Validation of this research approach is reflected in peer-reviewed support from the U.S. government in the form of two awarded grants. We are confident our public-private partnership with UTHSC will continue to flourish and potentially lead to Veru clinical programs in the coming years.”

“A core research principle at UTHSC is to develop new therapeutics that can overcome existing clinical challenges in cancer indications,” said Dr. Wei Li, Ph.D., Principal Investigator and UTHSC Distinguished Professor of Pharmaceutical Sciences and Director of the Drug Discovery Center. “We are very excited to receive significant federal grants that enable us to advance our research in metastatic prostate cancer, metastatic breast cancer and drug-resistant ovarian cancer. We are committed to collaborating with our clinical partner, Veru, who may ultimately pursue for late-stage clinical drug development.”

About Veru Inc.

Veru is a late clinical stage 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 2b/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 2b/3 study of enobosarm in nonmeasurable bone only metastatic breast cancer.

Infectious disease program focuses viral acute respiratory distress syndrome caused by SARS-CoV-2, Influenza, and RSV as well as 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. In April 2023, the Company reached agreement with FDA on design of Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS. The Company plans to initiate this Phase 3 clinical study in 2H 2023.

- **Influenza:** The Company is planning a Phase 3 clinical trial to evaluate sabizabulin in hospitalized influenza patients at high risk for ARDS.
- **Smallpox and Ebola viruses:** The Company is planning a pre-IND meeting with FDA to discuss the development of sabizabulin for smallpox virus and Ebola virus under the Animal Rule FDA regulatory approval pathway.

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: whether the development by UTHSC will produce any compounds that Veru will choose to further develop and whether any such further development will lead to any approval or commercialization of any such compound potentially deriving from the research collaboration between UTHSC and Veru; what indications, if any, such UTHSC research may focus on or produce meaningful results in; the planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company's current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 2b/3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2 metastatic breast cancer, the Phase 2b/3 study of enobosarm in bone-only non-measurable hormone receptor and HER2- metastatic breast cancer, the Phase 3 study of sabizabulin in hospitalized influenza patients at high risk of ARDS, and studies of sabizabulin in smallpox virus and Ebola virus, and whether any of such studies will meet any of its primary or secondary endpoint; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients will occur and what the results of any such interim analyses will be; whether the results of such interim analyses or the completed confirmatory Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA; whether and when any potential EUA or NDA would be granted; 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 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 sabizabulin will become a treatment for broad ARDS; whether the Company's FC2 telemedicine portal sales will grow or replace prior revenue from the U.S. prescription sales of FC2; whether the Company will recover any of the monies owed it by The Pill Club; whether and when the Company will receive the remaining installments from Blue Water in connection with the sale of ENTADFI or will receive any of the potential sales milestones related thereto; whether, when and how many shares may be sold under the Lincoln Park Capital Fund equity line; 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.

Investor Contact:

Samuel Fisch

Executive Director, Investor Relations and Corporate Communications

Email: veruinvestor@verupharma.com

Media Contact:

Hannah Gendel

Manager, Corporate Communications

Email: media@verupharma.com



Source: Veru Inc.