April 19, 2023

Veru Enters Into Supply Agreement with Afaxys to Expand Access to FC2 Female Condom® in U.S. Public Health Sector

MIAMI, FL, April 19, 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 that has a commercial sexual health division, today announced it has entered into a Purchasing Agreement with Afaxys Group Services, LLC (AGS) to offer Veru's FC2 Female Condom® (internal condom) through the AGS Group Purchasing Organization (GPO) for the benefit of up to 31 million women and men that depend on community and public health centers for essential healthcare. Afaxys is a trusted, mission-driven healthcare company that uniquely partners with those who serve community and public health patients to ensure access to affordable sexual and reproductive healthcare.

Under the terms of the agreement, Afaxys members will have access to a preferred pricing model for Veru's FC2 Female Condom®, an FDA-approved method of contraception indicated for preventing pregnancy and the transmission of sexually transmitted infections, including HIV/AIDS. As a result, Afaxys' healthcare provider membership is guaranteed reliable and affordable access to the FC2 Female Condom® for their patients.

"We applaud Afaxys for growing its portfolio of contraceptive product offerings with the addition of a non-hormonal contraceptive method, the FC2 Female Condom," said Mitchell Steiner, M.D., Chairman, President, and Chief Executive Officer of Veru. "This partnership will bring affordability and accessibility to family planning clinics, community health centers, and qualified private practices serving underrepresented women, an important and large U.S. public sector channel."

*"*As a socially conscious company, Afaxys ensures affordable access to sexual and reproductive healthcare is a right, not a privilege, for all patients," said Angela Hensel, Executive Director Afaxys Group Services. "We are proud to collaborate with Veru to help ensure this unique contraceptive option is available to meet the needs of our Afaxys GPO members."

The FC2 Female Condom® telehealth portal is available at www.fc2condoms.com. Pharmacists can order FC2 Female Condom from major wholesale distributors.

About FC2 Female Condom® (internal condom)

The FC2 Female Condom® (internal condom) is the only FDA-approved birth control option that protects against unintended pregnancy and sexually transmitted infections, including HIV/AIDS. FC2 is a hormone-free, latex-free female internal condom that puts women in control of their reproductive health and well-being. FC2 is available nationwide and can be easily accessed by obtaining a prescription through telemedicine or a local healthcare provider. FC2 is widely accepted with an estimated 750 million condoms being sold worldwide and is also approved by United Nations Population Fund and the World Health Organization as a prophylactic against sexually transmitted infections and as a family planning tool.

About Veru Inc.
Veru is a biopharmaceutical company focused on developing novel medicines for oncology focusing on breast cancer and for SARS-CoV-2 and other viral and ARDS-related diseases.

Oncology program
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

- **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.

- **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 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: the size of the potential market for FC2 through the collaboration with Afaxys; whether any of the Company’s current or planned clinical trials for any of its drug candidates will demonstrate sufficient efficacy and safety to warrant approval by the FDA or continued development, as the case may be, and whether and when any planned clinical trials will commence or any current or planned clinical trials will read out data; 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; 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.

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.