February 23, 2021

Veru Submits New Drug Application for Proprietary TADFIN for BPH

--TADFIN™, *Tadalafil 5mg and Finasteride 5mg formulated capsule, for daily oral dosing to improve compliance*--

--Administration of *Tadalafil and Finasteride is more effective than Finasteride alone to treat symptoms of benign prostatic hyperplasia*--

--FDA PDUFA Date is expected in December 2021--

--Plan to launch TADFIN, if approved, via telemedicine channels and to outlicense--

--TADFIN revenues will be part of Veru's sexual health commercial business--

MIAMI, Feb. 23, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer and breast cancer, today announced that it has submitted a 505(b)(2) New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for TADFIN™ (tadalafil 5mg and finasteride 5mg) capsules, a novel oral daily dosing combination formulation, for the treatment of benign prostatic hyperplasia (BPH).

"The submission of TADFIN, the Company's first NDA submission, is a significant milestone and a major step toward expanding the revenues for our sexual health commercial business —revenues we have used to substantially invest in the clinical development of our prostate and breast cancer drug candidates," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer. "We believe FDA approval of TADFIN is possible toward the end of the current calendar year, with a launch shortly thereafter via telemedicine or out-license of product to specialty pharmaceutical companies."

Dr. Steiner further added: "Veru is focused on delivering on our deep and promising late-stage oncology pipeline."

TADFIN combines both tadalafil 5mg and finasteride 5mg into one capsule formulation. CIALIS® (tadalafil) tablets, for oral use (Eli Lily and Company) is currently approved for treatment of BPH and erectile dysfunction and PROSCAR® (finasteride) tablets (Merck & Co., Inc.) is currently approved for treatment of BPH and PROPECIA® (finasteride) tablets for oral use for male pattern hair loss (androgenic alopecia) in men only (Merck & Co., Inc).

As previously announced, Veru received a waiver of the FDA NDA PDUFA filing fees, worth

approximately $2.4 million in cost savings, as a first-time filer. If approved, the Company currently plans to launch TADFIN through third-party telemedicine sales channels, and outlicensing opportunities thus eliminating the need for and cost of a direct sales force.

About Veru Inc.
Veru Inc. is an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate cancer and breast cancer. The Veru prostate cancer pipeline includes VERU-111, VERU-100, and Zuclomiphene citrate. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules for the treatment of metastatic castration and androgen receptor resistant prostate cancer. VERU-100 is a novel, proprietary peptide formulation designed to address the current limitations of commercially available androgen deprivation therapies (ADT) for advanced prostate cancer. Zuclomiphene citrate is an oral nonsteroidal estrogen receptor agonist being developed to treat hot flashes, a common side effect caused by ADT in men with advanced prostate cancer. The Veru breast cancer pipeline includes enobosarm for AR+/ER+/HER2- metastatic breast cancer and VERU-111 for taxane resistant metastatic triple negative breast cancer. Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets and activates the androgen receptor in AR+/ER+/HER2- metastatic breast cancer without unwanted masculinizing side effects. VERU-111 is also being advanced into Phase 3 for the treatment of hospitalized patients with COVID-19 who are at high risk for acute respiratory distress syndrome.

The Company's Sexual Health Business commercial product is the FC2 Female Condom®/ FC2 Internal Condom ("FC2"), an FDA-approved product for the dual protection against unintended pregnancy and the transmission of sexually transmitted infections. The Company's Female Health Company Division markets and sells FC2 commercially and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple third-party telemedicine and internet pharmacy providers and retail pharmacies. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world. The NDA was submitted in February 2021 for TADFIN™ (tadalafil 5mg and finasteride 5mg) capsule for the administration of tadalafil 5mg and finasteride 5mg combination formulation dosed daily for benign prostatic hyperplasia (BPH). Tadalafil (CIALIS®) is currently approved for treatment of BPH and erectile dysfunction and finasteride is currently approved for treatment of BPH (finasteride 5mg PROSCAR®) and male pattern hair loss (finasteride 1mg PROPECIA®). If approved, revenues from TADFIN (tadalafil 5mg and finasteride 5mg) capsule and the current revenues from the FC2 business will be combined in our sexual health commercial business. To learn more about Veru products, please visit www.verupharma.com.

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995:
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 regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for FDA submissions and approvals, preclinical and clinical study results including potential benefits and the absence of adverse events, the depth of the Company's drug pipeline, statements regarding the formulation and manufacturing of TADFIN and satisfaction of the regulatory

requirements for approval of TADFIN, the anticipated FDA acceptance of the preclinical studies and such design and scope, the ability of the Company to successfully launch and commercialize TADFIN and implement the Company's sales plans for TADFIN and statements regarding the Company's financial resources and operational capability to manufacture and commercialize TADFIN and its other drug candidates. Any forward-looking statements in this release are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this release. The Company assumes no obligation to update any forward-looking statements contained in this release because of new information or future events, developments or circumstances. Such forward-looking statements are subject to known and unknown risks, uncertainties and assumptions. If any such risks or uncertainties materialize or if any of the assumptions prove incorrect, our actual results could differ materially from those expressed or implied by such statements. Factors that may cause actual results to differ materially from those contemplated by such forward-looking statements include, but are not limited to, the following: risks related to the development of the Company's product portfolio, including clinical trials, regulatory approvals and time and cost to bring to market; potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies due to COVID-19, and the risk that such results will not support marketing approval and commercialization; potential delays in the timing of any submission to the FDA and regulatory approval of products under development and the risk that disruptions at the FDA caused by the COVID-19 pandemic may delay the review of submissions or approvals for new drugs; the risk of a delay or failure in reaching agreement with the FDA on the design of a clinical trial or in obtaining authorization to commence a clinical trial; preclinical or clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all; our pursuit of a COVID-19 treatment candidate is at an early stage and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all; risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated; government entities may take actions that directly or indirectly have the effect of limiting opportunities for VERU-111 as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments; the risk that the Company's products may not be commercially successful; risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable; risks relating to the ability of the Company to obtain sufficient financing on acceptable terms when needed to fund development and operations, including our ability to secure timely grant or other funding to develop VERU-111 as a potential COVID-19 treatment; product demand and market acceptance; competition in the Company's markets and therapeutic areas and the risk of new or existing competitors with greater resources and capabilities and new competitive product approvals and/or introductions; the risk that the Company will be affected by regulatory developments, including a reclassification of products; *price erosion, both from competing products and increased government pricing pressures; manufacturing and quality control problems; compliance and regulatory matters, including costs and delays resulting from extensive governmental regulation, and effects of healthcare insurance and*

regulation, including reductions in reimbursement and coverage or reclassification of products; some of the Company's products are in development and the Company may fail to successfully commercialize such products; risks related to intellectual property, including the uncertainty of obtaining patents, the effectiveness of the patents or other intellectual property protections and ability to enforce them against third parties, the uncertainty regarding patent coverages, the possibility of infringing a third party's patents or other intellectual property rights, and licensing risks; government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments; the risk 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; a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public sector customers may order and purchase fewer units than the full maximum tender amount or award; penalties and/or debarment for failure to satisfy tender awards; 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; risks related to concentration of accounts receivable with our largest customers and the collection of those receivables; the economic and business environment and the impact of government pressures; risks involved in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers; 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; risks related to the 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 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, 2020 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.

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Source: Veru Inc.