December 13, 2021

Veru Announces FDA Approval of ENTADFI, a New Treatment for Benign Prostatic Hyperplasia

--ENTADFI (Finasteride and Tadalafil) Capsules to Treat Benign Prostatic Hyperplasia--

--Commercialization Will Start Early Calendar Year 2022--

--ENTADFI to Be Marketed and Distributed by Veru's Direct to Patient Telemedicine and Telepharmacy Services Platform--

--Veru Partners with GoodRx, a National Healthcare Company that Operates a Telemedicine Platform that Connects Patients to Over 75,000 US Pharmacies--

MIAMI, Dec. 13, 2021 (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, announced today that the U.S. Food and Drug Administration (FDA) has approved ENTADFI™ for the treatment of urinary tract symptoms caused by an enlarged prostate called benign prostatic hyperplasia (BPH).

ENTADFI (finasteride and tadalafil) capsule for oral use has also been shown to be more effective to treat urinary tract symptoms caused by BPH with less potential for adverse sexual side effects compared to finasteride monotherapy. ENTADFI dosing is one capsule orally once a day, and the FDA approved indication is to initiate treatment of the signs and symptoms of benign prostatic hyperplasia in men with an enlarged prostate for up to 26 weeks.

ENTADFI will be marketed and distributed by Veru's own direct to patient telemedicine and telepharmacy services platform. Veru has also partnered with GoodRx®, a US based digital resource for healthcare, to reach their almost 20 million monthly visitors, which include both consumers and healthcare providers, and offer a unique cash price to ensure our treatment is more affordable and accessible.

"FDA approval of ENTADFI, a new treatment for BPH, is a significant execution milestone for Veru and an important step in expanding revenues from our commercial Sexual Health Division. We use these revenues to invest and advance our late clinical stage oncology drug pipeline portfolio as well as our global Phase 3 COVID clinical study," said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer. "We are in the process of

augmenting our marketing and sales efforts by adding commercialization partners in the US and ex-US. We expect to begin commercialization in early calendar year 2022. The treatment of BPH is an annual multi-billion dollar market with over 45 million US prescriptions filled each year and is projected to continue to grow with an aging male population."

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 is comprised of enobosarm, a selective androgen receptor targeting agonist, and sabizabulin, a cytoskeleton disruptor, and includes: the ongoing Phase 3 ARTEST study of enobosarm in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (3rd line metastatic setting); the planned Phase 2b study of sabizabulin in AR+ ER+ HER2- metastatic breast cancer with AR < 40% (3rd line metastatic setting); the planned Phase 3 ENABLAR-2 study of enobosarm + abemaciclib (a CDK 4/6 inhibitor) in AR+ ER+ HER2- metastatic breast cancer with AR ≥ 40% (2nd line metastatic setting); and the planned Phase 2 study of sabizabulin + enobosarm combination therapy in metastatic triple negative breast cancer after two systemic chemotherapies.

The Company has identified that patients who have ≥ 40% androgen receptor nuclei staining by immunohistochemistry, which is a measure of AR expression, in their breast cancer tissue are the patients that are most likely to respond to enobosarm. Based on this observation, the Company is developing a companion diagnostic test to determine a patient's AR expression status. Consequently, the Company has partnered with Roche/Ventana Diagnostics, a world leader in oncology companion diagnostic tests, who will develop and, if approved, commercialize the companion diagnostic AR test. The companion diagnostic test is being developed in parallel with the Phase 3 ARTEST clinical study.

The Company's late-stage prostate cancer development portfolio is comprised of sabizabulin, VERU-100, a long-acting GnRH antagonist, and zuclomiphene citrate, an oral nonsteroidal estrogen receptor agonist and includes: the ongoing Phase 3 VERACITY and Phase 2 studies of sabizabulin in metastatic castration and androgen receptor targeting agent resistant prostate cancer prior to IV chemotherapy; the ongoing Phase 2 dose finding study of VERU-100 in advanced hormone sensitive prostate cancer; and the planned Phase 2b study of zuclomiphene citrate in men with advanced prostate cancer on androgen deprivation therapy who suffer from hot flashes.

One of the Company's anticancer drugs, sabizabulin, also has dual antiviral and anti-inflammatory effects and is currently enrolling in a Phase 3 study for the potential treatment of hospitalized COVID-19 patients at high risk for acute respiratory distress syndrome (ARDS).

Veru also has a commercial Sexual Health Division which includes 2 FDA approved products: ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia in the U.S., 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: when commercial launch of ENTADFI will occur; the magnitude of any potential revenues generated by ENTADFI; 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; and whether the companion diagnostic for enobosarm will be developed successfully or be approved by the FDA for use. 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 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, 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. The Company disclaims any intent or obligation to update these forward-looking statements.

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