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Veru Announces Nature Medicine Publication Demonstrating that Enobosarm, an Androgen Receptor Targeted Agent, Inhibits Hormone Receptor Positive Metastatic Breast Cancer that has Become Resistant to Estrogen Receptor Targeted Endocrine and CDK4/6 Inhibitor Therapies

--International Study Establishes the Role of Androgen Receptor as a Tumor Suppressor in ER+ Advanced Breast Cancer--

--Preclinical Studies Support Enobosarm's Novel Mechanism of Action as an AR Activating Agent as a Potential Therapy in Patients with ER+ Metastatic Breast Cancer that have Become Resistant to Current Standard of Care Treatments--

--Veru Also Announces that the Enobosarm Phase 3 Registration ARTEST Study is on Track to Commence Next Quarter in Patients with Metastatic ER+ Breast Cancer that is Resistant to Estrogen Receptor Targeted Endocrine Therapy and CDK4/6 Inhibitors--

MIAMI, Jan. 19, 2021 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), an oncology biopharmaceutical company with a focus on developing novel medicines for the management of prostate and breast cancer, today announced the online publication of an article in *Nature Medicine*, Volume 27, Issue 2, February, 2021, entitled: "The Androgen Receptor is a Tumor Suppressor in Estrogen Receptor-Positive Breast Cancer" (https://www.nature.com/articles/s41591-020-01168-7 or DOI # 10.1038/s41591-020-01168-7) by an international team headed by Drs. Theresa Hickey and Wayne Tilley at the University of Adelaide in collaboration with scientists at the Garvan Institute of Medical Research in Australia.

In the *Nature Medicine* publication, Dr. Hickey and colleagues provide scientific evidence supporting a new discovery in breast cancer demonstrating that the androgen receptor acts like a tumor suppressor. Using human cell line and patient derived breast cancer models, they demonstrate that androgen receptor activation by androgens and enobosarm, a

selective androgen receptor agonist, had potent antitumor activity in all ER positive breast cancer preclinical models tested including those that have become resistant to estrogen receptor targeted endocrine therapy as well as CDK 4/6 inhibitors, which are standard of care treatments for advanced, ER+ breast cancer. Further, enobosarm, by activating the androgen receptor, has demonstrated antitumor activity in both estrogen receptor targeted endocrine therapy resistant and CDK4/6 inhibitor resistant metastatic human breast cancer models. In contrast, androgen receptor inhibitors, like enzalutamide, had no effect. This study clears up the confusion in the scientific field regarding the role that the androgen receptor is playing in ER+ breast cancer.

“We provide compelling new experimental evidence that androgen receptor activating drugs, like enobosarm, can be more effective than existing (e.g., Tamoxifen) or new (e.g., Palbociclib) standard-of-care treatments and, in the case of the latter, can be combined to enhance growth inhibition. Moreover, enobosarm as a selective androgen receptor activating agent lacks the undesirable masculinizing side effects of natural androgens and has potential additional clinical benefits in women including promotion of bone, muscle and physical function, and mental health,” said Professor Wayne Tilley, Director of the Dame Roma Mitchell Cancer Research Laboratories, and Associate Professor Theresa Hickey, Head of the Breast Cancer Group, who led the *Nature Medicine* study.

“This important new work establishes that the androgen receptor is a tumor suppressor and that enobosarm, as an AR targeted agent, has anti-tumor activity not only in AR+ ER+ metastatic breast cancer that has become resistant to estrogen receptor targeted endocrine and CDK4/6 inhibitor treatments, but also that enobosarm in combination with a CDK4/6 inhibitor (e.g. Palbociclib) restores CDK4/6 inhibitor sensitivity in ER+ breast cancer that has become resistant to CDK4/6 inhibition,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru. “I would like to congratulate Dr. Tilley and his international team for this landmark study which provides deep scientific evidence for the novel therapeutic approach Veru has taken to address estrogen receptor targeted endocrine therapy and CDK4/6 inhibitor resistance in patients with AR+ ER+ metastatic breast cancer. We are excited to be advancing enobosarm, our AR activating targeted agent, into a Phase 3 registration ARTEST clinical trial scheduled for next quarter.”

Enobosarm is an oral, first-in-class, new chemical entity, selective androgen receptor targeting agonist that activates the androgen receptor in AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects and has potentially beneficial effects including increase in muscle mass and physical function and the promotion of bone strength and healing. Enobosarm is the first new class of targeted endocrine therapy for advanced breast cancer in decades. Last quarter the FDA agreed to the ARTEST Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, a selective androgen receptor targeted agent, versus physician’s choice of either exemestane or tamoxifen as an active comparator for the treatment of metastatic ER+/HER2- breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. The primary endpoint is radiographic progression-free survival.

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. VERU-111 is being evaluated in open label Phase 1b and Phase 2 clinical trials in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer. The Phase 1b clinical trial completed enrollment of 39 men and is ongoing. The Phase 2 clinical trial has completed the enrollment of 40 men who have metastatic castration resistant prostate cancer and who have also become resistant to at least one novel androgen receptor targeting agent, such as abiraterone or enzalutamide, but prior to IV chemotherapy, and is ongoing. The Company anticipates proceeding to its Phase 3 VERU-111 VERACITY registration clinical trial in the first quarter of calendar 2021. VERU-111 is also being evaluated in a Phase 2 clinical trial to assess the efficacy of VERU-111 in combating COVID-19 in subjects at high risk for ARDS. 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. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist administered as a small volume, subcutaneous 3-month depot injection without a loading dose. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration — a problem which occurs with currently approved luteinizing hormone-releasing hormone (LHRH) agonists used for ADT. There are no GnRH antagonists commercially approved beyond a one-month injection. A Phase 2 trial to evaluate VERU-100 dosing is anticipated to begin in the first quarter of calendar year 2021 and a Phase 3 registration clinical trial is anticipated to begin the second half of calendar year 2021. 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. Following an End of Phase 2 meeting with the FDA, the Company plans to advance Zuclomiphene citrate to a Phase 3 clinical trial in men with advanced prostate cancer who experience moderate to severe hot flashes.

The Veru breast cancer pipeline includes enobosarm for hormone sensitive metastatic 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 the androgen receptor in AR+/ER+/HER2- metastatic breast cancer without unwanted virilizing side effects. Enobosarm is the first new class of targeting endocrine therapy in advanced breast cancer in decades. The FDA has agreed to the Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agent, versus physician’s choice of either exemestane or tamoxifen as an active comparator for the treatment of metastatic ER+/HER2- breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole), fulvestrant, and a CDK4/6 inhibitor. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3, open label, randomized, active control trial is anticipated to commence in the second quarter of calendar year 2021. VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts alpha and beta tubulin subunits of microtubules and is not a substrate for P-glycoprotein drug resistance protein. Over expression of P-glycoprotein is a common mechanism that results in taxane resistance in TNBC. Using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies in a total of approximately 80 men, the Company plans to meet with the FDA in the first half of calendar year 2021 and to commence a Phase 2b registration clinical trial in the second half of calendar year 2021 to evaluate oral daily dosing of VERU-111 in approximately 100 women with metastatic TNBC

that have become resistant to taxane IV chemotherapy.

Veru is also advancing a new drug formulation in its specialty pharmaceutical pipeline addressing unmet medical needs in urology such as the Tadalafil and Finasteride Combination (TADFYN®) 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®). The co-administration of tadalafil and finasteride has been shown to be more effective for the treatment of BPH than by finasteride alone. The Company expects to submit the NDA for TADFYN® in early calendar year 2021.

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. 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 clinical studies and FDA submissions, preclinical and clinical study results including potential benefits and the absence of adverse events and anticipated results of future clinical trials, and the anticipated design and scope for clinical trials and FDA acceptance of such design and scope. 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 COVID19, 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.