December 9, 2020

# Veru Expands Oncology Drug Pipeline; Exclusively Licenses Phase 3 Clinical Stage Targeted Therapy for Endocrine Resistant Metastatic Breast Cancer

***--Transformation to Premium Oncology Biopharmaceutical Company with Late-Stage Clinical Drug Pipeline Focused on Prostate and Breast Cancer is Complete--***

***--Company Poised to Initiate Four Oncology Drug Registration Trials in Prostate and Breast Cancer in Calendar Year 2021--***

***--Expects to Have Sufficient Resources to Fund AllClinical Development Including Four Potential Registration Trials Without Need for New Equity Financing to End of FY 2022—***

MIAMI, Dec. 09, 2020 (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 exclusively licensed worldwide rights to enobosarm, a late-stage oral novel androgen receptor (AR) targeting agent for the treatment of endocrine resistant ER+ HER2- metastatic breast cancer. The Company also provided an update on its clinical development program.

**Enobosarm for Endocrine Resistant ER+ / HER2- Metastatic Breast Cancer**

Enobosarm is an oral new chemical entity that selectively targets the AR in breast cancer without having the unwanted virilizing androgen adverse side effects including facial hair, acne, increase in hematocrit, or liver toxicity. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies in over 2,100 patients, including five prior Phase 2 clinical studies in advanced breast cancer. Two Phase 2 clinical studies were conducted in approximately 150 heavily pretreated patients with ER+ HER2- metastatic breast cancer who developed resistance to current estrogen endocrine therapy, with positive efficacy and safety clinical results.

The second Phase 2 clinical trial (G200802) was a 2-arm study evaluating 9 mg and 18 mg enobosarm daily oral dosing in 136 women with ER+ HER2- advanced breast cancer. The patients in this study were also heavily pretreated having failed an average of 4 endocrine treatments and 88% had received prior chemotherapy. The Primary Investigator for the study was Dr. Beth Overmoyer, Founder and Director of the Inflammatory Breast Cancer Program at the Dana-Farber Cancer Institute in Boston, Massachusetts, and Assistant

Professor of Medicine at Harvard Medical School. The completed Phase 2 study results, abstract # 811, “Efficacy and safety of enobosarm, a selective androgen receptor modulator, to target AR in women with advanced ER+/AR+ breast cancer - final results from an international Phase 2 randomized study” will be presented at the San Antonio Breast Cancer Symposium tomorrow, December 10th, at 2:15 pm eastern time, by Professor Carlo Palmieri, BSc, MB BS, PhD, FRC, Professor of Translational Oncology & Medical Oncologist, University of Liverpool.

Based on the efficacy and safety from these clinical studies, the FDA has recently agreed to the Company’s Phase 3 registration open label, randomized clinical trial, ARTEST clinical study, for evaluating the efficacy and safety of enobosarm, selective androgen receptor targeting agent, versus active comparator control (exemestane or tamoxifen) 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.

“Enobosarm represents the first new class of endocrine therapy for advanced breast cancer in decades. By targeting the AR in ER+ HER2- metastatic breast cancer, enobosarm introduces a novel endocrine therapy to patients with breast cancer that have exhausted endocrine therapies targeting ER, but prior to IV chemotherapy. We have successfully completed the exclusive in-license of full worldwide rights to enobosarm from the University of Tennessee Research Foundation and the Ohio State Research Foundation,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru Inc. “We are also pleased to have reached agreement with the FDA to initiate a single Phase 3 enobosarm 'ARTEST' registration clinical trial in ER+/HER2- metastatic breast cancer, which we expect to commence in the first half of calendar year 2021. Enobosarm has strong intellectual property protection with composition of matter patent expiry in 2029 and with possible 5-year patent extension to 2034 and method of use for breast cancer patents expiry 2034. The global annual market for an oral agent in an ER endocrine resistant setting is estimated to be $6 billion.”

Dr. Beth Overmoyer, MD, Founder and Director of the Inflammatory Breast Cancer Program at the Dana-Farber Cancer Institute, and Assistant Professor of Medicine, Harvard Medical School, said: “We are thrilled that Veru has acquired enobosarm, a new class of drugs that selectively targets the androgen receptor without causing unwanted virilizing side effects, and that the FDA has agreed to advance enobosarm into a registration Phase 3 trial for the treatment of hormone receptor positive metastatic breast cancer that has become resistant to endocrine therapy. Having led and participated in the prior two Phase 2 clinical studies involving approximately 150 heavily pretreated women in which enobosarm had demonstrated efficacy and was extremely well tolerated, we are excited both about the prospects of enobosarm in the Phase 3 trial and the potential for enobosarm to be an important therapeutic agent for women with metastatic breast cancer.”

**Drug Development Program Update**

**VERU-111 for Metastatic Castration and Androgen Receptor Targeting Agent Resistant Prostate Cancer**

VERU-111 is an oral, first-in-class, new chemical entity that targets, crosslinks, and disrupts

alpha and beta tubulin subunits of microtubules to disrupt the cytoskeleton. VERU-111 is being evaluated in open label Phase 1b and Phase 2 clinical studies in men with metastatic castration and androgen receptor targeting agent resistant prostate cancer. The Phase 1b clinical study completed enrollment of 39 men and is ongoing. The Phase 1b study has yielded promising efficacy and safety clinical data. Based on the Phase 1b study results, the recommended Phase 2 dose is 63mg oral daily continuous dosing for 21-day cycles. Daily chronic drug administration appears feasible and safe. At the recommended Phase 2 dose, there were no reports of neutropenia, neurotoxicity, or Grade 3 diarrhea. The efficacy results show PSA declines and responses as well as objective and durable tumor responses. Furthermore, the median treatment duration without cancer progression in men who had at least four cycles of VERU-111 is 11+ months.

In September, the Phase 2 clinical study completed enrollment of 41 men with metastatic castration resistant prostate cancer who have also become resistant to androgen receptor targeting agents, such as abiraterone, enzalutamide, and apalutamide, but prior to proceeding to IV chemotherapy. Although the study is still ongoing, daily chronic drug administration appears feasible and safe. At 63 mg daily continuous dosing, there were no reports of neutropenia, minor neurotoxicity, and manageable cases of diarrhea. Like the Phase 1b, the efficacy results show PSA declines and responses as well as objective and durable tumor responses. We plan to have more clinical data to report in the first half of 2021.

The Company had an FDA meeting in July 2020 and received positive input from the FDA on the pivotal Phase 3 trial design for VERU-111. The Company received regulatory clarity that the indication of treatment in men with metastatic castration resistant prostate cancer who have failed one androgen receptor targeting agent, but prior to IV chemotherapy was acceptable, that an open label, randomized study using an alternative androgen receptor targeting agent as the active control is reasonable, and that the primary endpoint may be radiographic progression-free survival. The Company anticipates starting the Phase 3 pivotal VERACITY study evaluating VERU-111 for men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent, in the first quarter of calendar year 2021.

Dr. Mark Markowski, MD, PhD, Assistant Professor of Oncology, The Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, said: “Our clinical experience with chronic oral daily dosing with VERU-111 shows that it is well tolerated and has promising evidence of efficacy in men with metastatic castration resistant prostate cancer who have progressed on prior androgen receptor targeting agents. We are excited that VERU-111 is advancing to a Phase 3 registration clinical trial. Developing new oral therapies in men with advanced metastatic prostate cancer is an unmet clinical need.”

**VERU-100 Androgen Deprivation Therapy for Advanced Prostate Cancer**

VERU-100 is a long-acting GnRH antagonist formulation administered as a small volume, subcutaneous three-month depot injection without a loading dose with multiple beneficial clinical attributes addressing the shortfalls of current FDA-approved androgen deprivation therapies (ADT) for advanced prostate cancer. VERU-100 immediately suppresses testosterone with no testosterone surge upon initial or repeated administration, a problem which occurs with currently approved LHRH agonists used for ADT. There are no GnRH

antagonist depot formulations commercially approved beyond a one-month duration 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 in the second half of calendar year 2021.

**VERU-111 for Taxane Resistant Metastatic Triple Negative Breast Cancer**

The Company has announced that the second oncology indication for the clinical development of VERU-111 will be metastatic triple negative breast cancer (TNBC), an aggressive form of breast cancer that occurs in 15% of all breast cancers. This form of breast cancer does not express ER, PR , or HER2 and is resistant to endocrine therapies. The first line of treatment usually includes IV taxane chemotherapy. Unfortunately, almost all women will eventually develop taxane resistant TNBC. Preclinical studies in human TNBC grown in animal models demonstrate that VERU-111 significantly inhibits cancer proliferation, migration, metastases, and invasion of tumors that have become resistant to paclitaxel (taxane). A poster is being presented this morning at 8 am eastern time at the San Antonio Breast Cancer Symposium virtual meeting on the preclinical efficacy data entitled: “VERU-111 as an orally available tubulin inhibitor suppressing both taxane sensitive and taxane resistant triple negative breast cancer” by Wei Li PhD, UTHSC Distinguished Professor and Director of UTCoP Drug Discovery Center, The University of Tennessee Health Science Center, 881 Madison Avenue, Memphis.

Using the safety information from the Phase 1b and Phase 2 VERU-111 prostate cancer clinical studies in a total of approximately 80 men, we plan to meet with the FDA in the first half of calendar 2021 to discuss a Phase 2b clinical trial design for possible accelerated approval for VERU-111 versus Trodelvy for patients with taxane resistant triple negative breast cancer, making the proposed trial a potential registration trial. The Phase 2b clinical study is planned to commence in the second half of calendar year 2021.

**Summary: Veru Has Transformed into a Late Clinical Stage Oncology Biopharmaceutical Company**

Dr. Steiner summarized: “Veru has evolved into a late clinical stage oncology biopharmaceutical company dedicated to the development and commercialization of drug candidates to address unmet medical needs for prostate and breast cancer management, and for which, we have made great progress. We are excited to have advanced our prostate cancer drug candidates, VERU-111 and VERU-100, as well as our breast cancer drug candidates, the recently acquired Enobosarm and the new additional indication for VERU-111, into registration clinical studies. Veru anticipates a total of 4 registration clinical trials for 4 oncology indications commencing in calendar year 2021:

- VERU-111 for the treatment of men with metastatic castration resistant prostate cancer who have also become resistant to one androgen receptor targeting agent - Planned Phase 3 VERACITY study first quarter calendar 2021;
- VERU-100 as androgen deprivation therapy for the palliative treatment of advanced prostate cancer- Planned Phase 2 first quarter calendar 2021 and planned Phase 3 fourth quarter calendar 2021;
- Enobosarm, selective androgen receptor targeting agent, for the treatment of ER+/HER2- metastatic breast cancer - Planned Phase 3 ARTEST study in the first half of calendar year 2021; and

- VERU-111 for the treatment of taxane resistant metastatic triple negative breast cancer - Planned Phase 2b in the second half of calendar year 2021.

We expect to fund all four of these registration trials from existing sources of cash, anticipated cash flow from operations, and the proceeds from our recent sale of PREBOOST®, without the need for a new equity financing, until at least the end of fiscal year 2022."

The Company does not expect to update the guidance provided above regarding its expectation that it will not need new equity financing. The Company notes that the statements of future performance made in this release are based upon current expectations and are subject to factors that could cause actual results to differ materially from those suggested here, including those factors set forth in the "Safe Harbor" Statement below.

**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. 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 (AR) 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. In October 2020, the FDA agreed to the Phase 3 registration clinical trial design to evaluate the efficacy and safety of enobosarm, selective androgen receptor targeting agent, versus exemestane or tamoxifen for the treatment of metastatic ER+/HER2- breast cancer in approximately 240 patients who have failed a nonsteroidal aromatase inhibitor (anastrozole or letrozole) and fulvestrant that have previously responded to hormone therapy. The primary endpoint is radiographic progression-free survival. The pivotal Phase 3, open label, randomized, active control trial is anticipated to commence in the first half 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 Company’s anticipation that it will not need new equity financing until at least the end of fiscal year 2022, the regulatory pathway to secure FDA approval of the Company's drug candidates, the anticipated timeframe for clinical studies and FDA submissions, clinical study results including potential benefits and the absence of adverse events, 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 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; 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; 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, 2019 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](www.verupharma.com/investors).*

Contact:
Sam Fisch, Director of Investor Relations
800-972-0538

Source: Veru Inc.