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Veru Reports Clinical Data from the Discontinued ARTEST Study of Enobosarm, Novel Selective Androgen Receptor Targeting Agonist, in AR+ ER+ HER2- Metastatic Breast Cancer

--Overall response rates of 12.5% are observed in the enobosarm group in a heavily pretreated population versus no responses in the standard of care active control arm. On average, enobosarm or active control was given in the 4th line treatment in the metastatic setting which included a prior CDK 4/6 inhibitor combination--

--Overall response rate was 20% for enobosarm monotherapy versus 0% for standard of care active control in patients who had ≤3 lines of prior endocrine therapy in the metastatic setting--

--Enobosarm was generally well tolerated with no masculinizing adverse events or hematocrit increases--

--Company believes ARTEST clinical data further validates the evaluation of enobosarm in the Phase 3 ENABLAR-2 study which is given earlier in the treatment sequence as a 2nd line therapy in the metastatic setting targeting a larger patient population--

MIAMI, Sept. 11, 2023 (GLOBE NEWSWIRE) -- Veru Inc. (NASDAQ: VERU), a late clinical stage biopharmaceutical company focused on developing novel medicines for metastatic breast cancer and for viral induced acute respiratory distress syndrome (ARDS), today announced clinical data from the discontinued Phase 3 ARTEST clinical trial of enobosarm monotherapy for the 3rd line or greater in the metastatic setting of AR+ER+HER2- breast cancer. Enrollment was discontinued in order to prioritize and focus the clinical development of enobosarm therapy earlier in the treatment sequence, the 2nd line metastatic setting, for AR+ER+HER2- metastatic breast cancer in the Phase 3 ENABLAR-2 (enobosarm +/- abemaciclib CDK 4/6 inhibitor) study. Data reported from the discontinued trial, which is based on an analysis of available data, may not be predictive of the results of larger, later-stage controlled clinical trials.

Highlights of clinical data from discontinued Phase 3 ARTEST clinical study

At the time enrollment was stopped, there were 34 evaluable patients randomized to either 9mg enobosarm monotherapy (n=16) or a standard of care active control (n=18) in the Phase 3 open label, randomized (1:1) clinical trial for the treatment of AR+ER+HER2- metastatic breast cancer with sufficient AR expression in their breast cancer tissue who had previously received at least a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

Active control treatment group received an average of 2.6 (range 1-5) and enobosarm 9mg monotherapy an average of 2.9 (range 1-5) prior lines of treatment. On average, enobosarm or the active control was given in the 4th line treatment for AR+ER+HER2- metastatic breast cancer.

Summary of Overall Response Rate Data*:

	Enobosarm monotherapy	**Estrogen blocking agent active control**
Evaluable patients	2 PR /16 (12.5%)	0 PR/18 (0%)
Evaluable patients - including an unconfirmed response	3 PR /16 (18.8%)	0 PR/18 (0%)
Patients with ≤3 lines of prior endocrine therapy	2 PR /10 (20%)	0 PR/15 (0%)
Patients with ≤3 lines of prior endocrine therapy with ≤1 prior treatment with CDK 4/6 inhibitor	2 PR /6 (33.3%)	0 PR/10 (0%)

*unaudited data, overall response rate = partial response (PR) + complete response (CR)

Safety: Enobosarm monotherapy was generally well tolerated without masculinizing adverse events or increases in hematocrit.

“Enobosarm is a new and different hormone agent that targets the androgen receptor to suppress metastatic breast cancer with potential improvements in quality of life without the unwanted masculinizing side effects and increase in hematocrit typically associated with androgens,” said Mitchell Steiner, M.D., Chairman, President and Chief Executive Officer of Veru.

“The clinical results from the ARTEST study provide promising scientific support and validation for the potential of enobosarm therapy in the ongoing Phase 3 ENABLAR-2 study. The AR+ER+HER2- metastatic breast cancer patients enrolled in the Phase 3 ARTEST study were heavily pretreated. On average, either enobosarm or the standard of care active control in ARTEST was given as 4th line treatment. Although sicker patients and smaller sample size, the antitumor activity and safety of enobosarm are promising. Tumor response rates of 20% for enobosarm monotherapy versus 0% for active control in patients with ≤3 lines of prior therapy are highly encouraging because they represent a patient population that is similar to that being tested in ENABLAR-2. Additionally, this is consistent with what we observed in the Phase 2 (G200802) study where enobosarm treatment resulted in a tumor response rate of 3/10 (30%) in a subgroup of heavily pretreated ER+HER2- metastatic breast cancer patients who also had a prior CDK 4/6 inhibitor. To put these tumor response rates into context, it has been reported that treatment with either elacestrant (selective

estrogen receptor degrader) or standard of care treatment in the 2nd line metastatic setting in ER+HER2- metastatic patients who had tumor progression following CDK 4/6 inhibitor treatment resulted in tumor response rates of about 4.5%."

"Based on the ARTEST study, our expectation for the ENABLAR-2 study is that enobosarm could have greater activity either as monotherapy or in combination with abemaciclib compared to an estrogen blocking agent active control earlier in the treatment sequence, 2nd line treatment, for AR+ER+HER2- metastatic breast cancer after receiving a prior CDK 4/6 inhibitor + estrogen blocking agent. In fact, in stage 1 of the ENABLAR-2 study, we have already observed 2 partial responses in the first 3 patients enrolled who were treated with enobosarm 9mg plus abemaciclib combination in the 2nd line metastatic setting after having tumor progression while receiving CDK 4/6 inhibitor plus an estrogen blocking agent. We are encouraged by these early results, and it appears to be the right decision to move and focus enobosarm's clinical development earlier to the 2nd line metastatic setting for ER+HER2- metastatic breast cancer patients in the Phase 3 ENABLAR-2 study."

About Enobosarm

Estrogen receptor (ER) is present in 85% of all breast cancers, and more than 90% of ER+ positive breast cancers also contain the AR which has been demonstrated to be an important therapeutic target in ER+ breast cancer. Enobosarm is an oral drug 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, while having potential clinical benefits including increasing muscle and physical function as well addressing cancer treatment induced bone loss and fractures. Enobosarm has extensive nonclinical and clinical experience having been evaluated in 25 separate clinical studies with approximately 1450 dosed patients, including three Phase 2 clinical studies in advanced breast cancer.

About Phase 3 ENABLAR-2 clinical study:

Phase 3 clinical ENABLAR-2 study – Enobosarm +/- abemaciclib (CDK 4/6 inhibitor) combination versus estrogen blocking agent (active control) as a 2nd line treatment for AR+ ER+ HER2- metastatic breast cancer

In March 2023, the Company announced that it was prioritizing the clinical development of enobosarm in the Phase 3 ENABLAR-2 (enobosarm +/- abemaciclib CDK 4/6 inhibitor) in the 2nd line metastatic setting in AR+ER+HER2- breast cancer and discontinuing the Phase 3 ARTEST (enobosarm monotherapy) clinical study in the 3rd line metastatic setting in AR+ER+HER2- breast cancer. Reasons the company prioritized the development of enobosarm in the Phase 3 ENABLAR-2 study included:

- The desire to focus enobosarm treatment earlier in a potentially more responsive, 2nd line metastatic setting in the sequence of therapies for patients with ER+HER2- breast cancer
- 2nd line treatment is a larger patient population than 3rd line or greater in the metastatic setting for ER+HER2- breast cancer
- The Phase 3 ENABLAR-2 and the Phase 3 ARTEST studies had an overlapping target patient population based on current and evolving standards of care, therefore closing

the ARTEST study would decrease competition for the recruitment of similar patients
- Veru has a clinical collaboration and supply agreement for abemaciclib with Eli Lilly for the Phase 3 ENABLAR-2 study

On March 30, 2023, the Company met with the FDA to gain further agreement on Phase 3 clinical trial design and program. The Phase 3 study has been amended to accommodate the FDA's latest recommendations to support registration as a second line treatment for patients with AR+ ER+ HER2- metastatic breast cancer who have tumor progression while receiving a CDK 4/6 inhibitor plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The Phase 3 ENABLAR-2 study has 2 distinct study stages:

In Stage 1 of the Phase 3 study which will enroll 160 patients, the objectives are to optimize the dose of enobosarm in the abemaciclib combination and to assess the efficacy of enobosarm as a monotherapy compared to an estrogen blocking agent active control. The primary endpoint for Stage 1 is ORR. The Stage 1 initial run-in enrolled 3 patients to assess the safety and pharmacokinetics of the abemaciclib + enobosarm 9mg combination. In this run-in portion, there were no drug-to-drug interactions between abemaciclib and enobosarm, and there were no new safety findings. Further, the early preliminary clinical results showed 2 partial responses and 1 stable disease in the first 3 patients based on local assessments, and all patients have been on study for over 9 months. Our current plan is to have Phase 3 Stage 1 clinical results by late 2024 or early 2025. If enobosarm monotherapy or abemaciclib + enobosarm combination therapy compared to estrogen blocking agent (active control) demonstrates significant improvement in ORR, which is considered a surrogate endpoint for clinical benefit, then the Company plans to meet with the FDA to consider an accelerated approval regulatory pathway based on the clinical data from the Stage 1 portion of the Phase 3 study.

In Stage 2 of the Phase 3 study, we plan to enroll approximately 200 subjects in a multicenter, open label, randomized (1:1), active control clinical study, to evaluate the efficacy and safety of enobosarm with or without abemaciclib therapy (depending on the outcome of Stage 1) versus an alternative estrogen blocking agent (selective estrogen receptor degrader or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed a CDK 4/6 inhibitor plus an estrogen blocking agent (nonsteroidal aromatase inhibitor or selective estrogen receptor degrader). The primary endpoint for Stage 2 of the Phase 3 study is progression-free survival.

In January 2022, Veru entered into a clinical trial collaboration and supply agreement through which Eli Lilly supplies abemaciclib for the ENABLAR-2 trial.

About Veru Inc.
Veru is a late clinical stage biopharmaceutical company focused on developing novel medicines for metastatic breast cancer and for viral ARDS.

Oncology program: metastatic breast cancer

The Company's late-stage breast cancer development portfolio comprises enobosarm, a selective androgen receptor targeting agonist.

- Enrolling Phase 3 clinical ENABLAR-2 study – enobosarm +/- abemaciclib combination

versus estrogen blocking agent (active control) as a 2nd line treatment in AR+ ER+ HER2- metastatic breast cancer. The Company and Eli Lilly and Company have entered into a clinical study collaboration and supply agreement for the ENABLAR-2 study. Lilly supplies Verzenio® (abemaciclib).

Infectious disease program: viral ARDS

- **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. In April 2023, the Company reached agreement with FDA on design of the Phase 3 confirmatory COVID-19 clinical trial to evaluate sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS. Although the Company has reached agreement with FDA for the design of Phase 3 confirmatory COVID-19 clinical trial, the Company now plans to meet with FDA to reach agreement on the design of a proposed expanded Phase 3 confirmatory study evaluating sabizabulin 9mg for the treatment of hospitalized adult patients who have and type of viral lung infection and on oxygen support who are at high risk for ARDS and death. The FDA has granted a meeting with Veru for September 2023.
- **Smallpox and Ebola viruses:** The Company is planning a pre-IND meeting with FDA to discuss the development of sabizabulin for Ebola virus under the Animal Rule FDA regulatory approval pathway. Veru had pre-IND meeting with FDA in August for smallpox virus. FDA agreed that the Animal Rule pathway is acceptable for evaluating the efficacy of smallpox virus. The Company will work with FDA to develop a plan for the nonclinical studies that could support a smallpox indication.

Sexual health program – Urev

Veru has a commercial sexual health division called Urev that is comprised of 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. The Company has launched its own independent, FC2-dedicated direct to patient telehealth and pharmacy services portal. The Company is focused on executing new contracts with additional telehealth partners and has internet fulfillment pharmacy partners that provide coverage in all 50 states in the U.S.

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 planned design, enrollment, timing, commencement, interim and full data readout timing, scope, regulatory pathways, and results of the Company's current and planned clinical trials, including the confirmatory Phase 3 study of sabizabulin for certain COVID-19 patients, the Phase 3 study of enobosarm in combination with abemaciclib for the 2nd line treatment of AR+ ER+ HER2

metastatic breast cancer, the Phase 3 study of enobosarm in bone-only non-measurable hormone receptor and HER2- metastatic breast cancer, the Phase 3 study of sabizabulin in hospitalized influenza patients at high risk of ARDS, and studies of sabizabulin in smallpox virus and Ebola virus, and whether any of such studies will meet any of its primary or secondary endpoint; whether the ENABLAR-2 study will show results consistent with or greater than the ARTEST results reported above; whether and when any of the planned interim analyses in the planned Phase 3 confirmatory study of sabizabulin for certain COVID patients will occur and what the results of any such interim analyses will be; whether the results of such interim analyses or the completed confirmatory Phase 3 study or any other interim data will be sufficient to support a new EUA application or an NDA; whether and when the Company will expand the study of sabizabulin into other ARDS indications; whether and when the Company will receive the future installment payments of the ENTADFI purchase price or sales milestone payments; and the outlook for growth in the Company's FC2 business through telehealth customers, our direct to patient telehealth portal and the global public health sector. 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 or other ARDS 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 or other ARDS treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 or other ARDS treatments; the Company's existing products, including FC2 and, if authorized, sabizabulin, and any future products, if approved, possibly not being commercially successful; 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, development costs, and market awareness and acceptance of any telehealth platform we develop; risks relating to our ability to increase sales of FC2 after significant declines in recent periods due to telehealth industry consolidation and the bankruptcy of a large telehealth customer; 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, 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 and Media Contact:

Samuel Fisch
Executive Director, Investor Relations and Corporate Communications
Email: veruinvestor@verupharma.com

Source: Veru Inc.