September 20, 2021

Veru Announces Positive Updated Data from Phase 1b/2 Sabizabulin Study in Men with Metastatic Castration Resistant Prostate Cancer at the 2021 ESMO Congress

MIAMI, Sept. 20, 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 that updated clinical data from the positive Phase 1b/2 study of sabizabulin (VERU-111) in 80 men with metastatic castration resistant prostate cancer who have progressed on at least one novel androgen receptor targeting agent were presented at the European Society for Medical Oncology (ESMO) Congress 2021 being held September 16-21, 2021. Sabizabulin is a new oral chemical entity that represents a novel class of agents that target unique binding sites on microtubules to disrupt both the cytoskeleton and androgen receptor transport.

Highlights of the presentation:

The oral presentation provided an updated analysis of mature data that combines approximately 80 patients enrolled in both the Phase 1b and 2 portions of the study. Heavily pretreated patients were enrolled who had tumor progression on androgen deprivation therapy and a novel androgen receptor targeting agent (approximately 40% had tumor progression after at least 2 androgen receptor targeting agents).

As for safety, there were 54 men treated at the recommended Phase 2 dose of sabizabulin 63mg oral daily dosing in the Phase 1b/2 combined study. Sabizabulin was well tolerated with no clinically relevant neutropenia or neurotoxicity. The most common adverse events observed were gastrointestinal related (diarrhea, nausea and fatigue) which were predominantly Grades 1 and 2.

As for efficacy, combining patients in Phase 1b/2 study who received 63 mg sabizabulin daily with measurable metastatic disease at baseline (PCWG3 criteria), the median rPFS is estimated to be approximately 7.4 months (3.2 – 30.0+ months) as 5 patients remain on study of which two of which have been on sabizabulin without tumor progression for more than 2 years. In the Phase 1b/2 population with measurable disease at baseline per RECIST 1.1, the Overall Response Rate (ORR) was 21%.

Presentation details:

Presentation Date/Time: Mini Oral Session - Genitourinary Tumours, Prostate; September 19, 2021, 17:30-18:10 CEST
Abstract Title: Phase 1b/2 study of sabizabulin (VERU-111), an androgen receptor transport disruptor, in men with metastatic castration resistant prostate cancer who have progressed on an androgen receptor targeting agent
Presenter: Mark C. Markowski, M.D., PH.D., Assistant Professor of Oncology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
Abstract Number: 3087

Additional information on the meeting can be found on the ESMO website https://www.esmo.org/meetings/esmo-congress-2021

“The updated data from this clinical trial continue to demonstrate that daily oral sabizabulin administration is feasible and well tolerated,” said Dr. Mark Markowski, an Assistant Professor of Oncology at the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center and the presenter of these results. “Further, long term responses in this heavily pretreated patient population are demonstrative of the promising efficacy which is currently being tested in the Phase 3 VERACITY study,” said Dr. Markowski.

“These updated findings from our clinical study of sabizabulin continue to support the potential role of sabizabulin in filling a growing unmet medical need in the treatment of men with metastatic prostate cancer that have tumor progression with androgen deprivation and novel androgen receptor targeting agent therapy, but prior to IV chemotherapy. Based on this Phase 1b/2 study, sabizabulin has a safety profile similar to what has been reported in the literature for novel androgen receptor targeting agents and with promising efficacy. We are greatly anticipating the results of our ongoing Phase 3 VERACITY study which is enrolling in 45 clinical centers in the United States,” said Dr. Mitchell S. Steiner, Chairman, President and CEO of Veru Inc.

About VERACITY Phase 3 Clinical Trial
Sabizabulin is a novel oral new chemical entity that targets unique binding sites in microtubules to disrupt both the cytoskeleton and androgen receptor transport. In June 2021, the Company initiated the open label, randomized (2:1), multicenter Phase 3 VERACITY clinical trial evaluating sabizabulin 32mg versus an alternative androgen receptor targeting agent for the treatment of chemotherapy naïve men with metastatic castration resistant prostate cancer who have failed at least one androgen receptor targeting agent. The 32mg dose formulation being studied in the VERACITY study has similar bioavailability to the 63mg dose formulation used in the Phase 1b/2 study. The primary endpoint is median radiographic progression free survival. The Phase 3 VERACITY clinical trial is anticipated to enroll approximately 245 patients from 45 clinical centers.

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. Veru’s prostate cancer pipeline includes: sabizabulin, an oral, first-in-class, new chemical entity that targets the cytoskeleton which in prostate cancer also disrupts the transport of the androgen receptor. A Phase 3 VERACITY clinical trial evaluating the efficacy and safety of sabizabulin in approximately 245 men for the treatment of metastatic castration and androgen receptor targeting agent resistant prostate cancer is enrolling. VERU-100, a novel, proprietary gonadotropin releasing hormone antagonist peptide long acting 3-month subcutaneous

injection formulation for androgen deprivation therapy to treat hormone sensitive advanced prostate cancer, is currently enrolling in a Phase 2 clinical trial, and the Phase 3 clinical trial is planned to initiate in calendar Q4 2021. Veru's breast cancer pipeline includes: enobosarm, an oral, first-in-class, new chemical entity, selective androgen receptor agonist that targets the androgen receptor, a tumor suppressor, to treat AR+ER+HER2- metastatic breast cancer without unwanted masculinizing side effects. The enobosarm clinical program is initially focusing on 2 indications: 1) Phase 3 ARTEST clinical trial to evaluate enobosarm monotherapy in a 3rd line metastatic setting in approximately 210 subjects with AR+ER+HER2- metastatic breast cancer (≥ 40% AR positivity) who have failed nonsteroidal aromatase inhibitor, fulvestrant, and a CDK 4/6 inhibitor which is anticipated to commence soon; and 2) Phase 2b study to evaluate the efficacy and safety of enobosarm and CDK 4/6 inhibitor, abemaciclib, combination compared to estrogen blocking agent (Active Control) for the treatment of AR+ER+HER2- metastatic breast cancer in a 2nd line metastatic setting in approximately 186 patients who have failed 1st line treatment in a metastatic setting with CDK 4/6 inhibitor, palbociclib, in combination with either an aromatase inhibitor or fulvestrant which is expected to commence in calendar Q4 2021. Sabizabulin will also be evaluated in a three arm Phase 2b clinical study planned to initiate in calendar Q3 2021 to evaluate oral daily dosing of sabizabulin monotherapy and sabizabulin + Trodelvy® (sacituzumab govitecan-hziy) combination therapy versus Trodelvy® monotherapy in approximately 216 women with metastatic triple negative breast cancer that have become resistant to at least two systemic chemotherapies. Based on positive Phase 2 results on the reduction of mortality, sabizabulin is also being evaluated in a Phase 3 clinical trial for the treatment of hospitalized patients with moderate to severe COVID-19 who are at high risk for acute respiratory distress syndrome in approximately 300 subjects and is currently enrolling in the United States and South America.

The Company's Sexual Health Business commercial product is the FC2 Female Condom® (internal condom) (FC2), an FDA-approved product for 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 second potential commercial product, if approved, expected for the Sexual Health Business is TADFIN™ (tadalafil 5mg and finasteride 5mg capsule) dosed daily for benign prostatic hyperplasia (BPH). PDUFA date for the NDA is in December 2021. The Company plans to initially launch through telemedicine and telepharmacy sales channels. To learn more about Veru products, please visit www.verupharma.com.

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 whether future clinical development and results will demonstrate sufficient efficacy and safety and potential benefits to secure FDA approval of the Company's drug candidates, the anticipated design and scope for clinical trials and FDA acceptance of such design and scope, whether sabizabulin,

enobosarm, VERU-100 and TADFIN will serve any unmet need, what dosage, if any, might be approved for use in the US or elsewhere, and whether the commencement or enrollment timelines for the clinical trials will be met, and also statements about the potential, timing and efficacy of the rest of the Company's development pipeline, including the ability of the Company to successfully launch TADFIN. 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.

Trodelvy® (sacituzumab govitecan-hziy) is a registered trademark of Gilead Sciences, Inc.

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Source: Veru Inc.