



**FOR IMMEDIATE RELEASE**  
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**Promising New Treatment for Prostate Cancer Also Demonstrates  
Encouraging Results Against Triple Negative Breast Cancer**

*Efficacy Preclinical Studies Conducted by UTRF, UTHSC and Veru Inc.'s  
University-Industry Partnership*

**MEMPHIS, Tenn.** – A research collaboration between the University of Tennessee Health Science Center (UTHSC), the University of Tennessee Research Foundation (UTRF) and biopharmaceutical company Veru Inc. has resulted in a promising next generation oral cancer therapy, VERU-111, which has the potential to treat not only advanced prostate cancer, but other cancer types including triple negative breast cancer (TNBC).

The American Association for Cancer Research published an article presenting VERU-111's positive preclinical results against TNBC in their October edition of *Molecular Cancer Therapeutics*, a leading journal for the discovery and preclinical development of novel cancer treatments. Entitled "An orally available tubulin inhibitor, VERU-111, suppresses triple-negative breast cancer tumor growth and metastasis and bypasses taxane resistance," the published work combines expertise from the labs of Dr. Wei Li, professor of pharmaceutical sciences and Director of the UTHSC College of Pharmacy Drug Discovery Center, and Dr. Tiffany Seagroves, professor of pathology in the UTHSC College of Medicine. The research article's lead author is Shanshan Deng.

Although VERU-111 is currently being evaluated in advanced prostate cancer patients in an ongoing Phase 1b/2 clinical trial, the preclinical efficacy results against TNBC reported in *Molecular Cancer Therapeutics* provide further support that VERU-111 may also effectively treat other types of cancer. According to the publication, findings presented in the study "provide strong rationale for future development of VERU-111 as an effective treatment for this form of difficult to treat metastatic breast cancer."

The oral cancer therapy known as VERU-111 is a first-in-class selective small molecule that

targets and disrupts microtubules in cancer cells. Both in vitro and in vivo animal studies conducted by the UTHSC research team demonstrate the molecule's ability to inhibit tumor growth and metastasis, as well as overcome multidrug resistance. Moreover, these nonclinical studies show that VERU-111 does not appear to cause nerve damage (neurotoxicity) or neutropenia (severe reduction in white blood cells), both of which are serious side effects of certain chemotherapy agents (taxanes) currently used against TNBC.

“This new publication by Dr. Li’s team at UTHSC in this prestigious journal, *Molecular Cancer Therapeutics*, demonstrates the preclinical efficacy of VERU-111, a novel selective, oral antitubulin in triple negative breast cancer,” said Dr. Mitchell Steiner, Chairman, President and CEO of Veru Inc. “We are currently evaluating VERU-111 in men who have metastatic castration resistant prostate cancer in a Phase 1b/2 clinical trial and the early results appear promising.”

For UTRF, this research collaboration highlights the importance of intellectual property commercialization and showcases the promising potential of university-industry relationships. Vice President Richard Magid adds: “UTRF is proud to act as the bridge between university and industry in the drive to move this technology and others from lab to market. Despite considerable progress, there are still too many patients that still need effective cancer treatments. The ultimate goal of technology transfer is helping to turn innovative research into life-saving products.”

VERU-111 originated in the lab of Dr. Li, who worked with various other researchers to develop the molecule, notably Dr. Duane D. Miller, professor emeritus in the UTHSC Department of Pharmaceutical Sciences, and Dr. James T. Dalton, now Dean and Professor of Pharmaceutical Sciences in the University of Michigan’s College of Pharmacy. The drug molecule was subsequently patented and then licensed exclusively to Veru Inc., from which the drug gets its name.

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## **ABOUT UTHSC**

As Tennessee’s only public, statewide, academic health system, the mission of the University of Tennessee Health Science Center is to bring the benefits of the health sciences to the achievement and maintenance of human health through education, research, clinical care, and public service, with a focus on the citizens of Tennessee and the region. To learn more visit [www.uthsc.edu/](http://www.uthsc.edu/)

## **ABOUT UTRF**

UTRF is a non-profit 501(c)(3) organization that promotes the commercialization of UT intellectual property, encourages an entrepreneurial culture, contributes to state and regional

economic development, and promotes research and education to benefit the people of Tennessee and beyond. UTRF provides assistance and resources to the research activities of faculty, staff, and students of UT and works to help move ideas to the marketplace. To learn more visit [utrff.tennessee.edu/](http://utrff.tennessee.edu/)

## **ABOUT VERU INC.**

Veru Inc. is an oncology and urology biopharmaceutical company developing novel medicines for prostate cancer treatment and supportive care, as well as urology specialty pharmaceuticals. The Veru prostate cancer pipeline includes VERU-111, zuclomiphene citrate, and VERU-100. VERU-111 is an oral, next-generation, first-in-class selective small molecule that targets and disrupts alpha and beta tubulin subunits of microtubules in cells to treat metastatic prostate cancer patients whose disease is resistant to both castration and novel androgen blocking agents (abiraterone or enzalutamide). VERU-111 is being evaluated in men with metastatic castration and androgen-blocking agent resistant prostate cancer in an open label Phase 1b/2 clinical trial. Zuclomiphene citrate is an oral estrogen receptor agonist being evaluated in a Phase 2 trial to treat hot flashes, a common side effect caused by hormone treatment for men with advanced prostate cancer. VERU-100 is a novel, proprietary peptide formulation for androgen deprivation therapy (ADT) with multiple beneficial clinical attributes addressing the shortfalls of current FDA approved ADT formulations for advanced prostate cancer. VERU-100 is a long-acting gonadotropin-releasing hormone (GnRH) antagonist designed to be administered as a small volume subcutaneous 3-month depot injection without a loading dose. VERU-100 will immediately suppress testosterone with no testosterone surge upon initial or repeated administration --- a problem which occurs with currently approved LHRH agonists. Currently, there are no GnRH antagonists commercially approved beyond 1 month. VERU-100 is anticipated to enter a Phase 2 dose finding study in early 2020. To learn more about Veru's prostate cancer pipeline and other Veru products please visit [www.verupharma.com](http://www.verupharma.com).

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