



## **TARIS® Initiates Dosing of TAR-200 (GemRIS™) in Muscle-Invasive Bladder Cancer Patients Unfit for Curative Intent Therapy**

**LEXINGTON, Mass. – March 14, 2018 –** [TARIS](#) announced today that it has initiated dosing in a clinical trial of TAR-200 (GemRIS™) in patients with Muscle Invasive Bladder Cancer (MIBC) who are unfit for therapy with curative intent. MIBC is a serious and lethal form of bladder cancer, with limited treatment options. While some potentially curative treatments, including surgical organ removal and chemoradiation, are available, 40% or more of patients with this disease are unfit to undergo these morbid procedures, or opt to not receive them. Based on the positive preliminary results observed with TAR-200 in muscle-invasive bladder cancer patients, TARIS believes TAR-200 may offer a new option for these underserved patients.

This multi-center, multi-region study intends to enroll subjects with organ-confined, non-metastatic MIBC who are unfit for curative intent therapies. Subjects will be evaluated for safety, tolerability, and evidence of anti-tumor efficacy following 4 consecutive cycles of TAR-200. Subjects successfully completing this dosing period will then be eligible to receive additional maintenance dose cycles. More information on the study is available [here](#).

“This trial seeks to explore the utility of TAR-200 in patients who currently have few viable treatment options. Frail and elderly patients, who are diagnosed with MIBC and are unfit for curative intent therapy, often suffer from significant symptom burden and typically succumb to their disease. This innovative trial affords an opportunity to potentially address this devastating cancer and the challenging symptoms caused by this malignancy,” said Kirk A. Keegan, MD, MPH, Assistant Professor of Urologic Surgery at Vanderbilt University and the primary investigator for this trial.

“At TARIS, we are passionate about developing therapies for severely underserved patient populations. MIBC patients who are unfit for curative therapy suffer a significant deterioration in their health and rapidly progress to death. TARIS believes that TAR-200 may offer an entirely new approach to treating MIBC, without the serious morbidity that renders current therapies untenable for so many,” said Christopher Cutie, MD, Chief Medical Officer at TARIS. “In addition to initiating this important study, TARIS today also announced a research collaboration with Sweden’s Uppsala Clinical Research Center and Professor Per-Uno Malmström. This collaboration seeks to illuminate the natural history of MIBC, and to better understand the outcomes associated with an inability to receive potentially curative treatment.” More information on the research collaboration is available [here](#).

### **About Bladder Cancer**

Bladder cancer is the fifth most common neoplasm in industrialized countries, affecting roughly 2.7 million people worldwide. In the United States, there were an estimated 79,000 new cases and nearly 17,000 deaths in 2017; Muscle Invasive Bladder Cancer (MIBC) accounts for 20-25% of the newly diagnosed cases, and the majority of disease-related mortality. The standard of care for treatment of MIBC includes radical cystectomy (complete removal of the bladder), with or without neoadjuvant chemotherapy. Radical cystectomy is a major life changing surgery, and many patients are medically unfit and/or unwilling to undergo this procedure.

**About TAR-200 (GemRIS™)**

TAR-200 is TARIS's lead investigational program in bladder cancer, and is designed to release the chemotherapeutic agent gemcitabine continuously in the bladder for multiple weeks. TARIS believes the system has the potential to offer an improved therapeutic option for MIBC, especially for patients unfit for current standards of care.

**About TARIS Biomedical®**

TARIS Biomedical® is building a unique therapeutically-focused urology company, developing targeted new treatments for millions of patients suffering from difficult-to-treat bladder diseases. We are advancing therapies for debilitating conditions, including bladder cancer and overactive bladder, enabled by continuous local dosing where it is needed. [www.tarisbiomedical.com](http://www.tarisbiomedical.com)

**Company Contact**

Christopher J. Searcy  
Chief Business Officer  
(781) 676-7750  
[csearcy@tarisbio.com](mailto:csearcy@tarisbio.com)

###