



TARIS Biomedical® Launches Second Phase 1b Clinical Trial of TAR-200 (GemRIS™) in Patients with Bladder Cancer

Dosing Initiated in Non-Muscle-Invasive Bladder Cancer Trial

LEXINGTON, Mass. – August 10, 2016 – [TARIS Biomedical](#), a company developing powerful and targeted new treatments for millions of patients suffering from difficult-to-treat bladder diseases, announced today the initiation of a Phase 1b clinical trial of TAR-200 (GemRIS™, **Gemcitabine Releasing Intravesical System**) in patients with non-muscle-invasive bladder cancer (NMIBC). The study, which is being conducted in Europe, is the second Phase 1b trial of TAR-200 in bladder cancer. TARIS announced the initiation of a study in [muscle-invasive bladder cancer \(MIBC\)](#) in July 2016. TAR-200, a drug-device combination product utilizing the [TARIS® System](#), is designed to release gemcitabine continuously into the bladder over 7 days.

“Non-muscle-invasive bladder cancer, which represents 70-75% of newly diagnosed cases, is a serious disease with a profound impact on the lives of patients. The current management of this cancer includes repeated surgical and pharmacological interventions, as well as lifelong monitoring. Despite these efforts, many patients are still at risk of recurrence and, in some cases, progression to MIBC,” said Christopher J. Cutie, MD, Chief Medical Officer of TARIS. “TAR-200 may ultimately offer a unique non-surgical approach in the management of this disease.”

“The initiation of a second study of TAR-200 is another substantial milestone for our organization,” said Purnanand Sarma, Ph.D., President and Chief Executive Officer of TARIS. “If successful, these two studies are designed to demonstrate the potential utility of TAR-200 across the entire spectrum of bladder cancer. We are very excited to advance these programs into the clinic and look forward to the results.”

About the TAR-200 Phase 1b Trial

The Phase 1b open-label study will assess whether continuous, local exposure to gemcitabine using TAR-200 is safe and tolerable in patients with intermediate risk NMIBC. The study will also assess the preliminary efficacy and pharmacokinetics in this patient population. The study will be conducted at multiple sites in Europe and expects to enroll up to 30 patients after the diagnosis of NMIBC and before transurethral resection of bladder tumors (TURBT).

About TAR-200

TAR-200 (GemRIS™) is TARIS' first product candidate in bladder cancer. TAR-200 is a drug-device combination product designed to release gemcitabine continuously into the bladder over 7 days. Gemcitabine is commonly used to treat multiple cancers alone and in combination with other chemotherapeutic drugs.¹ TARIS believes TAR-200 has the potential to set a new standard of care in bladder cancer, with enhanced efficacy and minimal systemic side effects compared to current approaches. TARIS is developing TAR-200 to address unmet needs in both muscle-invasive and non-muscle-invasive bladder cancer.

About Non-Muscle-Invasive Bladder Cancer

Bladder cancer affects roughly 2.7 million people worldwide, including nearly 600,000 in the United States.² The National Cancer Institute estimates that there will be a total of nearly 77,000 new cases and 16,000 deaths due to this disease in 2016.³ When measured as a cumulative lifetime per patient cost, bladder cancer exceeds all other forms of cancer.⁴ The estimated U.S. national expenditure on bladder cancer was \$4.3 billion in 2014.⁵

Non-muscle-invasive bladder cancer (NMIBC) represents 70-75% of newly diagnosed cases. NMIBC tumors are confined to the innermost layers of the bladder wall, and have not progressed into the deeper muscle layer or beyond. These tumors are currently managed using local resection (transurethral resection of bladder tumors or TURBT) and local pharmacological intervention. While current treatments often eliminate the existing tumor(s), the disease frequently recurs, requiring lifelong monitoring and repeated intervention. Further, higher-risk tumors that recur or progress despite these therapies often require patients to undergo radical cystectomy (complete surgical removal of the bladder). Radical cystectomy is a major, life changing procedure, and many patients are medically unfit and/or unwilling to undergo this surgery.

About the TARIS® System

The TARIS® System is a controlled release dosage form for use in the bladder. The system uses passive delivery principles to continuously release drug in the bladder over weeks to months. It is deployed into and retrieved from the bladder using minimally invasive in-office procedures. This technology allows drug release to be tailored to match the needs of specific treatment regimens.

About TARIS Biomedical®

TARIS Biomedical® is building a unique therapeutically-focused urology company developing powerful and 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

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