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

Christopher J. Cutie, M.D., MBA, promoted to Chief Medical Officer

LEXINGTON, Mass. – July 13, 2016 – TARIS Biomedical LLC, 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™) in patients with muscle-invasive bladder cancer (MIBC). TAR-200, a drug-device combination product utilizing the TARIS® System, is designed to release gemcitabine continuously into the bladder over 7 days. TARIS® also announced that Christopher J. Cutie, M.D., MBA, has been promoted to Chief Medical Officer to oversee all of TARIS' clinical programs.

"Patients diagnosed with muscle-invasive bladder cancer often require complex treatment regimens, including systemic chemotherapy and radical cystectomy (complete surgical removal of the urinary bladder), a life-altering operation associated with significant morbidity and, in some cases, death. Unfortunately, one or both of these treatments are not suitable for many patients suffering from this potentially lethal disease," said Dr. Cutie. "TAR-200 has the potential to address patients underserved by the current standard of care."

"To our knowledge, this is the first time any drug has ever been continuously delivered into the bladder to treat a bladder tumor over such an extended period. We are excited about this novel treatment approach and look forward to seeing the results of this study," said Purnanand Sarma, Ph.D., President and Chief Executive Officer of TARIS. "Launching our first clinical trial in oncology is a significant milestone for TARIS. Building on the momentum from our Allergan transaction announced in 2014, we are rapidly expanding the organization and plan to move multiple programs into the clinic in the coming 12-18 months. We are pleased to recognize Dr. Cutie's superb leadership of our clinical programs with his promotion to Chief Medical Officer."

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 MIBC. The study will also assess the preliminary efficacy in this patient population. The study will be conducted at multiple sites in the U.S. and expects to enroll up to 20 patients after the diagnosis of MIBC and before radical cystectomy.

About TAR-200

TAR-200 (GemRIS™) is TARIS' first program 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 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, the expense to treat 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]

Muscle Invasive Bladder Cancer (MIBC) is an advanced form of the disease, representing 25-30% of the newly diagnosed cases. MIBC tumors, which have progressed into the muscle of the bladder wall and potentially beyond, may lead to metastases and death. The standard of care for treatment of MIBC includes radical cystectomy, or complete removal of the bladder, with or without neoadjuvant chemotherapy. Radical cystectomy is a major, life changing procedure and many patients are medically unfit and/or unwilling to undergo the procedure.

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

Company Contact
Christopher J. Searcy
Chief Business Officer
(781) 676-7750

Media Contact
Stefanie Tuck
MacDougall Biomedical Communications
(781) 235-3060

csearcy@tarisbio.com stuck@macbiocom.com

# # #

1) http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020509s033lbl.pdf
2) Botteman MF1, Pashos CL, Redaelli A, Laskin B, Hauser R. The health economics of bladder cancer: a comprehensive review of the published literature. Pharmacoeconomics. 2003;21(18):1315-30.
3) National Cancer Institute. Surveillance, Epidemiology, and End Results ProgramTurning Cancer Data Into Discovery. Cancer of the Urinary Bladder. http://seer.cancer.gov/statfacts/html/urinb.html. Accessed August 20, 2015.
4) Kemp TJ, Ludwig AT, Earel JK, et al. Neutrophil stimulation with Mycobacterium bovis bacillus Calmette-Guérin (BCG) results in the release of functional soluble TRAIL/Apo-2L. Blood. 2005 Nov 15; 106(10): 3474-3482.
5) Cancer Trends Progress Report. Financial Burden of Cancer Care. http://progressreport.cancer.gov/after/economic_burden. Accessed August 11, 2015.