



TARIS Biomedical® Announces Positive Results from Ph1b Trial of TAR-200 (GemRIS™) in Patients with Muscle Invasive Bladder Cancer

Company planning to rapidly enter later-stage clinical development

LEXINGTON, Mass. – January 6, 2017 – [TARIS Biomedical LLC](#), a company developing targeted new treatments for millions of patients suffering from difficult-to-treat bladder diseases, announced today that it has closed initial enrollment in its Phase 1b clinical trial of TAR-200 (GemRIS™) following highly positive results. TAR-200, a drug-device combination product utilizing the TARIS® System, is designed to release gemcitabine continuously into the bladder over 7 days. This open-label study assessed the safety and tolerability of TAR-200 when used in patients with MIBC following initial diagnosis and prior to radical cystectomy. In addition, the study evaluated anti-tumor activity at Day 28 of the study. The treatment regimen employed in this study included two system deployments separated by a 14-day rest period.

Preliminary results indicate that the system was well tolerated over two 7-day treatment periods, with no local or systemic tolerability findings. To be eligible for enrollment, patients were required to have visible bulky residual tumor of at least 3 cm in size, clinical stage T2 or T3. Striking tumor responses, including complete tumor ablation or substantial shrinkage, were observed visually at the time of cystectomy in 8 of 10 patients. While the study was originally designed to include up to 20 subjects, the company closed enrollment early following these positive results in order to accelerate the clinical advancement of TAR-200. The company expects complete data from this study, including histopathological assessment, to be presented at a major upcoming medical meeting.

“The results of this study are very exciting,” said Siamak Daneshmand, M.D., Associate Professor of Urology, University of Southern California, and Principal Investigator for the TAR-200-101 study. “TAR-200 appears to be remarkably well-tolerated in patients who have recently undergone extensive transurethral resection of the bladder. Moreover, the unexpected activity observed in these heavily diseased subjects in just 28 days indicates the significant potential of this product in a broad population of patients with MIBC, often a very difficult disease to treat.”

“TARIS is extremely excited about the compelling results from this study, and plans to rapidly advance the product into later-stage clinical trials in bladder cancer in 2017,” said Purnanand Sarma, Ph.D., President and CEO of TARIS. “The tumor response we have seen to date

suggests TAR-200 may offer a fundamentally new treatment option for patients with MIBC, where the current standard of care includes bladder removal. We share the excitement of the study investigators about the potential impact that TAR-200 may have on the lives of patients across the spectrum of bladder cancer.”

About the TAR-200-101 Phase 1b Trial

The Phase 1b open-label study was designed to assess whether continuous local exposure to gemcitabine is safe and tolerable in patients with MIBC. The study was initially designed to enroll up to 20 subjects across three sites in the US. Enrolled subjects had bulky residual clinical stage T2 or T3b MIBC tumors following initial transurethral resection of bladder tumor (TURBT), and were ineligible to receive cisplatin-based combination neoadjuvant chemotherapy. Subjects received two placements of TAR-200 during Days 1-7 and 21-28 in the 28-day window between TURBT and radical cystectomy. Subjects were evaluated for safety, tolerability, and evidence of antitumor effects.

About TAR-200

TAR-200 (GemRIS™) is TARIS Biomedical’s 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, and is routinely given intravenously¹. 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 surgery and many patients are medically unfit and/or unwilling to undergo this 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 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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