# U.S. FDA Grants Fast Track Designation to TARIS® for TAR-200 (GemRIS™) in Muscle Invasive Bladder Cancer

*Designation for Patients Unfit for Curative Intent Therapy*

**LEXINGTON, Mass. – April 03, 2018 –** TARIS today announced that the United States Food and Drug Administration (FDA) has granted Fast Track designation for TAR-200 (GemRIS™) for the treatment of patients with organ-confined or locally-advanced Muscle Invasive Bladder Cancer (MIBC) who are unfit for curative intent therapy. This designation offers TARIS earlier and more frequent opportunities to collaborate with the FDA to expedite development of TAR-200, bringing this treatment more quickly to the patients who need it. This status also provides an opportunity for Priority Review and submission of completed sections of a New Drug Application (NDA) on a rolling basis prior to completion of the full application.

Earlier this year, TARIS announced initiation of a clinical study of TAR-200 in MIBC patients unfit for curative intent therapy (link). Further, the company announced the commencement of a research collaboration with Sweden's Uppsala Clinical Research Center and Professor Per-Uno Malmström to understand the natural history of this patient population (link).

"This Fast Track designation reinforces the high unmet need in the treatment of muscle invasive bladder cancer patients, especially those who cannot receive curative intent therapy. It further highlights the potential of GemRIS to benefit this underserved population," said Purnanand Sarma, Ph.D., President and CEO of TARIS. "Taken together, the combination of Fast Track, our ongoing clinical study, and our research collaboration in Sweden, form the foundation to rapidly advance the development of GemRIS. We look forward to working closely with the FDA to bring this important therapy to patients as quickly as possible."

**About Muscle Invasive 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.

While some potentially curative treatments, including surgical organ removal and chemoradiation, are available, 40% or more of patients with MIBC are unfit to undergo these morbid procedures, or opt to not receive them.[i] Available treatment options for these patients are limited to palliative care.

**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.

**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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[i] Gray, PJ. et al. *Eur Urol*, 2013, 63(5), 823 - 829