

TARIS[®] Presents Data Demonstrating Significant Local and Systemic Immune Modulation Following Continuous Low-Dose Bladder Delivery of Gemcitabine

Late-Breaking Poster at American Association of Cancer Research Annual Meeting Local treatment of bladder tumor yields an immune-mediated ablation of distant tumor

LEXINGTON, Mass. – April 16, 2018 – TARIS today presented a late-breaking poster titled "Significant cytotoxic and immunomodulatory effects of continuous low-dose intravesical gemcitabine in rodent bladder tumor models," at the American Association of Cancer Research (AACR) Annual Meeting in Chicago. The poster was presented during the session <u>LBPO.IM01 - Late-Breaking Research:</u> <u>Immunology 1</u>, Poster Section 45, Board #19 from 8:00 AM - 12:00 PM.

The preclinical data presented in the poster demonstrated powerful and unique antitumor biology that can be elicited via continuous, targeted delivery of gemcitabine into the urinary bladder. Specifically, the research detailed three key findings:

- Continuous perfusion of low-dose gemcitabine directly into rodent bladders was associated with significant ablation of the primary tumor and a marked shift in tumor microenvironment from a T Regulator dominant to a more T Effector dominant profile
- 2) When rodents were simultaneously implanted with bladder and flank tumors, local delivery of gemcitabine into the bladder also led to arrest and ablation of the distant flank tumor, suggesting a dynamic immune-mediated systemic antitumor activity
- 3) When rodents were implanted with flank tumors 14 days after local treatment of their primary bladder tumors, flank tumors failed to grow and were completely ablated, further confirming systemic antitumor activity following local gemcitabine delivery

"To our knowledge, these data are the first demonstration of continuous, low-dose gemcitabine resulting in potent cytotoxicity as well as systemic immune modulation," said Dennis Giesing, PhD, Chief Scientific Officer of TARIS. "While immune effects on the local tumor microenvironment are significant, the systemic antitumor activity suggests the bladder has a rich immune potential that can be further exploited."

"Data presented today demonstrate our ability to unlock novel bladder biology, which we believe may translate into a significant clinical benefit," said Purnanand Sarma, PhD, President & CEO of TARIS. "We are excited about our GemRIS[™] program, currently under investigation in the clinic for the treatment of muscle invasive bladder cancer (MIBC) in patients ineligible for curative intent therapy, and our planned clinical research collaboration with Bristol Myers Squibb to study the combination of GemRIS[™] and Opdivo[®] in MIBC."

About Muscle Invasive Bladder Cancer (MIBC)

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 product 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. <u>www.tarisbiomedical.com</u>

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