TARIS Announces Positive Topline Data for TAR-302 in Patients with Idiopathic Overactive Bladder

First-of-its-kind therapy provides continuous treatment directly into the bladder and shows promise for patients with limited treatment options

LEXINGTON, Mass. – August 28, 2018 – TARIS, a biopharmaceutical company developing transformational therapies to treat people with debilitating urological disorders, today announced positive preliminary safety and efficacy data from its clinical study of TAR-302 for the treatment of patients with idiopathic overactive bladder (OAB) refractory to oral therapy. Subjects in the Phase 1b study received a single TAR-302 system, which provides continuous local dosing of the approved antimuscarinic agent trospium into the bladder. Subjects who were experiencing an average of more than five daily urge incontinence episodes demonstrated a reduction in mean daily episodes of 75% following dosing for 42 days (p=0.0049). Based on the unmet need in this disease state and the efficacy demonstrated in this study on established endpoints, TARIS plans to rapidly advance this program into later stage trials.

“The results of this study suggest TAR-302 may come to represent an innovative new approach to treating overactive bladder,” said Michael J. Kennelly, M.D., FACS, Professor of Urology at Carolinas Medical Center, Medical Director of the Charlotte Continence Center and Women’s Center of Pelvic Heath, and Principal Investigator of the TAR-302 clinical studies. “There is a substantial need for alternative options in the management of OAB when patients fail oral therapies. The compelling efficacy observed to date with TAR-302, in the absence of side-effects, represents a potentially significant advance in the development of improved therapies for these patients.”

In the multi-center study, TAR-302 was deployed into the bladder on day zero and continuously released drug for 42 days. Preliminary data in 11 subjects with a moderate to severe burden of disease who had failed multiple oral agents demonstrated:

- A reduction in mean daily incontinence episodes of 75%
- Substantial, clinically meaningful reductions in patient-reported symptom bother, and commensurate increases in health-related quality of life measures
- Negligible systemic drug exposure throughout the study
- TAR-302 was well tolerated

“TAR-302 is a validation of our commitment to develop transformational therapies to treat people with serious urological disorders,” said Purnanand Sarma, Ph.D., President & CEO, TARIS. “Current approaches to treating these diseases, including overactive bladder, are inadequate and often result in poor quality of life. These study data continue to support TARIS’ ability to access disease targets through continuous local therapy. By unlocking novel epithelial biology at the site of the disease, we may be able to fundamentally redefine the management of OAB, a debilitating condition for millions of patients.”

TARIS plans to present full results of this study at an upcoming scientific meeting.

About Overactive Bladder
One out of every six American adults suffers from symptoms of overactive bladder (OAB).[i] OAB is characterized by urinary urgency, frequency and incontinence; these symptoms have a profound negative impact on patients' daily activities and quality of life. OAB can result from an underlying neurologic injury (neurogenic detrusor overactivity, or NDO) or from unclear etiology (idiopathic overactive bladder, or iOAB). Antimuscarinic agents are available in oral and transdermal dosage forms, but their utility is limited by systemic side effects.

About TAR-302
TAR-302 is TARIS' lead investigational program in overactive bladder and is designed to continuously release the antimuscarinic agent trospium in the bladder for three months, at local concentrations several times higher than achievable with oral treatment. TARIS believes that TAR-302 has the potential to improve efficacy, reduce side effects, and unlock powerful new pharmacology compared with oral therapy. TARIS is evaluating TAR-302 to address unmet needs in both idiopathic and neurogenic OAB.

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 and targets the site of disease, potentially offering a safer and more efficacious treatment option for patients.

About TARIS Biomedical®
TARIS is developing transformational therapies to treat people with debilitating urological disorders. The company is unlocking novel epithelial biology through continuous disease engagement with its unique platform. TARIS' lead programs in bladder cancer and overactive bladder position the company to improve patient health and redefine urologic care.
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[i] Stewart WF, World J Urol (2003) May;20(6):327-36