Sumitomo Pharma

Sumitomo Pharma Announces Positive Topline Results from Phase 3 Clinical Studies Evaluating Vibegron in Men with Overactive Bladder Symptoms Receiving Pharmacological Therapy for Benign Prostatic Hyperplasia

–Vibegron Met Both Co-Primary Endpoints Demonstrating Statistically Significant Reductions in Daily Micturition and Urgency Episodes, Compared to Placebo at Week 12–
–Vibegron Met All Secondary Endpoints, Including a Reduction in Nocturia Episodes Versus Placebo at Week 12–
–Open-label Extension Trial Showed Reductions in Daily Micturition and Urgency Episodes Were Maintained Up to 52 Weeks–
–Vibegron Was Well-Tolerated and Demonstrated a Consistent Safety Profile with No New Safety Signals Compared to Prior Overactive Bladder Studies–

Cambridge, Mass., and Basel, Switzerland, September 11, 2023 – Sumitomo Pharma Co., Ltd. companies, Sumitomo Pharma America, Inc. (SMPA) and Sumitomo Pharma Switzerland (SMPS), announced today that the Phase 3 URO-901-3005 clinical study of vibegron (GEMTESA®), a beta-3 adrenergic receptor (β3) agonist, dosed once-daily (75 mg), which is being investigated in men with overactive bladder (OAB) symptoms receiving pharmacological therapy for benign prostatic hyperplasia (BPH), met its co-primary endpoints at Week 12 compared to placebo. The co-primary endpoints include both change from baseline in the average number of micturition (urination) episodes per day and change from baseline in the average number of urgency episodes (the sudden urge to urinate that is difficult to control) per day.

URO-901-3005 was a Phase 3 multicenter, randomized, double-blind, parallel-group, fixed-dose study which evaluated the efficacy, safety, and tolerability of vibegron versus placebo over 24 weeks in 1,105 men with OAB symptoms receiving pharmacological therapy for BPH. In the primary efficacy analysis, once-daily vibegron met the co-primary endpoints at Week 12, demonstrating statistically significant reductions from baseline (least squares means) in daily micturitions (-2.04 [SE: 0.109]; $p<0.0001$) and in daily urgency episodes (-2.88 [SE: 0.164]; $p<0.0001$) compared to placebo (-1.30 [SE: 0.109] and -1.93 [SE: 0.164], respectively).

In the study, patients receiving vibegron met all secondary endpoints at Week 12, including a statistically significant reduction in the key secondary endpoint of average number of nocturia episodes per night compared to placebo (-0.88 compared to -0.66; $p=0.0015$). Additionally, patients receiving vibegron showed statistically significant reductions from baseline compared to placebo in the average number of urge urinary incontinence episodes per day (-2.19 compared to -

1.39; p=0.0034) and International Prostate Symptom Storage score (-3.0 compared to -2.1; p<0.0001), while a statistically significant increase was seen in the average volume voided per micturition (25.63 mL compared to 10.56 mL; p<0.0001).

“Millions of men struggle with the burdensome symptoms of OAB which are further exacerbated by BPH, including frequent and urgent need to urinate, difficulty or delay in urinating, and waking up in the middle of the night to urinate. These symptoms can have a significant negative impact on patients’ lives, including long-term sleep deprivation,” said Armin Szegedi, M.D., Ph.D., Chief Medical Officer at SMPA. “These data from URO-901-3005 demonstrate the potential of vibegron and speaks to our commitment to addressing the unmet needs of those experiencing urologic conditions.”

“We are pleased to share the results of this study, which underscores the promise of one of our key marketed assets beyond its initial approved indication,” said Myrtle Potter, President and Chief Executive Officer of SMPA. “With these positive data, we look forward to exploring the potential of vibegron as an option for men experiencing OAB symptoms and BPH.”

The safety and tolerability of vibegron was assessed throughout the study. Overall, vibegron was well-tolerated throughout the study and demonstrated a consistent safety profile with no new safety signals compared to prior OAB studies. The most common adverse events occurring in at least 2% of the vibegron 75 mg group and at a rate higher than placebo were hypertension (9.0% and 8.3%, respectively), COVID-19 (4.0% and 3.1%, respectively), and urinary tract infection (2.5% and 2.2%, respectively). The frequency of serious adverse events was similar across treatment arms (4.3% in vibegron, 2.9% in placebo).

“OAB is often misconstrued as a normal part of aging instead of a clinical condition,” said Adele Gulfo, Chief Executive Officer of Biopharma Commercial Unit at SMPA. “Since its launch, vibegron has helped more than 200,000 patients and long-term care residents living with OAB. We are committed to continued innovation and bringing novel treatment options to those living with often underdiscussed urologic conditions.”

Patients who completed URO-901-3005 were eligible to continue onto URO-901-3006, an open-label, 28-week extension study evaluating the safety, tolerability, and efficacy of vibegron 75 mg in men with symptoms of OAB who are receiving pharmacological therapy for BPH. Results from the

open-label extension study show reductions in the average number of micturitions per day and urgency episodes per day were maintained up to 52 weeks. Reductions in nocturia, urge urinary incontinence, International Prostate Symptom Storage score, and increase in average volume voided per micturition were also maintained up to 52 weeks. Overall, vibegron was well-tolerated throughout the study and demonstrated a consistent safety profile with no new safety signals compared to prior studies.

Results will be presented at future medical congresses. Use of GEMTESA in men with symptoms of OAB receiving pharmacological therapy for BPH is not approved and its safety and efficacy have not been evaluated by regulatory authorities.

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About GEMTESA (vibegron)

Vibegron, a once-daily beta-3 adrenergic receptor (β3) agonist, is currently under investigation for the treatment of men with overactive bladder (OAB) symptoms receiving pharmacological therapy for benign prostatic hyperplasia in the United States (U.S.). In the U.S., GEMTESA (vibegron) has been indicated for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults since April 2021. GEMTESA works by selectively targeting β3 adrenergic receptors to reduce OAB symptoms through the relaxation of the bladder detrusor muscle to increase capacity. In China, vibegron is currently under investigation in a Phase 3 clinical study for the treatment of OAB.

About Overactive Bladder

Overactive bladder (OAB) is a clinical condition that occurs when the bladder muscle contracts involuntarily. Symptoms may include urinary urgency (the sudden urge to urinate that is difficult to control), urgency incontinence (unintentional loss of urine immediately after an urgent need to urinate), and frequent urination (usually eight or more times in 24 hours).[1] About 33 million U.S. adults experience the bothersome symptoms of OAB.[2]

About Benign Prostatic Hyperplasia

Benign prostatic hyperplasia (BPH) is a condition in men in which the prostate gland is enlarged. About 60% of men with BPH are treated for lower urinary tract symptoms (LUTS).[3,4] LUTS can be divided into storage, voiding, and postmicturition symptoms.[5] Over half of men with BPH report storage symptoms and about a quarter report voiding symptoms.[4] This suggests that many men with

a diagnosis of BPH may have overactive bladder.[4] Many men who are treated for symptoms are assumed to have an obstruction in the bladder caused by an enlarged prostate.[3,4] About half of all men between ages 51 and 60 have BPH and up to 90% of men over age 80 are living with the condition.[6]

INDICATIONS AND USAGE

GEMTESA is a beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of the product.

WARNINGS AND PRECAUTIONS

Urinary Retention

Urinary retention has been reported in patients taking GEMTESA. The risk of urinary retention may be increased in patients with bladder outlet obstruction and also in patients taking muscarinic antagonist medications for the treatment of OAB. Monitor patients for signs and symptoms of urinary retention, particularly in patients with bladder outlet obstruction and patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

ADVERSE REACTIONS

Most common adverse reactions (≥2%) reported with GEMTESA were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

Please see full Prescribing Information.

About Sumitomo Pharma America, Inc.

Sumitomo Pharma America (SMPA) is focused on delivering therapeutic and scientific breakthroughs in areas of critical patient need spanning psychiatry & neurology, oncology, urology, women's health, rare disease, and cell & gene therapies. The company's diverse portfolio includes several marketed products and a robust pipeline of early- to late-stage assets. SMPA leverages

proprietary in-house advanced analytics and computational technology platforms to accelerate discovery, research, and help bring novel therapies to patients sooner. SMPA is a Sumitomo Pharma Co., Ltd., company. For more information on SMPA, visit our website https://www.us.sumitomo-pharma.com or follow us on LinkedIn.

About Sumitomo Pharma Co., Ltd.

Sumitomo Pharma is among the top-ten listed pharmaceutical companies in Japan, operating globally in major pharmaceutical markets, including Japan, the U.S., China, and other Asian countries with about 6,000 employees worldwide. Sumitomo Pharma Group defines its Mission as "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." Additional information about Sumitomo Pharma is available through its corporate website at https://www.sumitomo-pharma.com.

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For a copy of this release, visit Sumitomo Pharma America's website at www.us.sumitomo-pharma.com.

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