Sumitomo Pharma America Announces U.S. FDA Approval of GEMTESA® (vibegron) for Men with Overactive Bladder Symptoms Receiving Pharmacological Therapy for Benign Prostatic Hyperplasia

– GEMTESA® is the first and only beta-3 agonist approved for the treatment of men with OAB symptoms who are receiving pharmacological therapy for BPH –

MARLBOROUGH, Mass., December 23, 2024 -- Sumitomo Pharma America, Inc. (SMPA) announced today that the U.S. Food and Drug Administration (FDA) has approved GEMTESA® (vibegron), a beta-3 (β_3) adrenergic receptor agonist, dosed once-daily (75 mg), for the treatment of men with overactive bladder (OAB) symptoms, such as urge urinary incontinence, urgency, and urinary frequency, who are receiving pharmacological therapy for benign prostatic hyperplasia (BPH). This approval marks GEMTESA as the first and only β_3 agonist approved to treat patients living with OAB and being treated for BPH. It is currently available for prescription in the U.S.

BPH is increasingly prevalent in men as they get older, and OAB symptoms, which could be associated with BPH, can often be mistaken as a natural part of aging. There are about 14 million men in the U.S. living with BPH, and up to 75% of them have clinical symptoms of OAB.[1,2] OAB symptoms may go unnoticed in men, especially if they have BPH.[3] In fact, ~80% of OAB cases in men may go undiagnosed.[4]

“Millions of patients suffer from OAB along with existing BPH. OAB is a urological condition that has limited treatment options to address their symptoms and impact on their social life.” said Tsutomu Nakagawa, Ph.D., President and Chief Executive Officer of SMPA. “The FDA’s expanded approval of GEMTESA is an important milestone for the men with unresolved symptoms of OAB while being treated for BPH, which underscores our urgency to deliver for those affected by conditions with unmet need."

The FDA’s approval of GEMTESA is based on results from URO-901-3005, a Phase 3 study of vibegron versus placebo over 24 weeks in approximately 1,100 men with OAB symptoms receiving pharmacological therapy for BPH. The study met all co-primary endpoints at Week 12, demonstrating statistically significant reductions from baseline in the average number of micturition (urination) episodes per day and in the average number of daily urgency episodes (sudden urge to urinate that is difficult to control) compared to placebo.[5] An additional endpoint showed a reduction in instances of urge urinary incontinence episodes (unintentional loss of urine immediately after an urgent need to urinate) per day at 12 weeks.[5] Adverse reactions, exceeding placebo rate, reported in ≥2% of patients treated with GEMTESA were hypertension and urinary tract infection.[5]

Please see Important Safety Information below.

“The clinical data on once-daily vibegron demonstrated clear improvements in key OAB symptoms in patients also receiving pharmacological therapy for BPH, showcasing the potential of GEMTESA to offer patients a way to gain better control of their symptoms,” said Yumi Sato, Chief Development Officer, SMPA. “With this FDA approval and launch of the first β_3 agonist for men with OAB symptoms being pharmacologically treated for BPH, we have the potential to give men living with this disease a life with fewer interruptions due to their OAB symptoms.”

GEMTESA (vibegron) is currently approved for OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults, and is now available for prescription in the U.S. for the treatment of men with OAB being pharmacologically treated for BPH.

IMPORTANT SAFETY INFORMATION
CONTRAINDICATIONS
GEMTESA is contraindicated in patients with known hypersensitivity to vibegron or any components of GEMTESA. Hypersensitivity reactions, such as angioedema, have occurred.

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 or patients taking muscarinic antagonist medications for the treatment of OAB. Discontinue GEMTESA in patients who develop urinary retention.

Angioedema
Angioedema of the face and/or larynx has been reported with GEMTESA. Angioedema has been reported to occur hours after the first dose or after multiple doses. Angioedema, associated with upper airway swelling, may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, immediately discontinue GEMTESA and provide appropriate therapy and/or measures necessary to ensure a patent airway.

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

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.
• overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH).

Please click here for full Prescribing Information.

About GEMTESA® (vibegron)
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 was approved on December 18, 2024, for overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia (BPH). GEMTESA works by selectively targeting β_3 adrenergic receptors to reduce OAB symptoms through the relaxation of the bladder detrusor muscle to increase capacity.

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).[6] Approximately 33 million U.S. adults experience the bothersome symptoms of OAB.[7]

About Benign Prostatic Hyperplasia
Benign prostatic hyperplasia (BPH) is a condition in men in which the prostate gland is enlarged. Many men who are treated for symptoms are assumed to have an obstruction in the bladder caused by an enlarged prostate.[3,4] Even when the obstruction is alleviated by BPH treatment, unresolved symptoms of OAB may persist. 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.[8] More than half of men with LUTS 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]

About Sumitomo Pharma
Sumitomo Pharma Co., Ltd., is a global pharmaceutical company based in Japan with key operations in the U.S. (Sumitomo Pharma America, Inc.), Canada (Sumitomo Pharma Canada, Inc.), and Europe (Sumitomo Pharma Switzerland GmbH) focused on addressing patient needs in oncology, urology, women's health, rare diseases, psychiatry & neurology, and cell & gene therapies. With several marketed products in the U.S., Canada, and Europe, a diverse pipeline of early- to late-stage assets, we aim to accelerate discovery, research, and development to bring novel therapies to patients sooner. For more information on SMPA, visit our website https://www.us.sumitomo-pharma.com or follow us on LinkedIn.]

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