## Gemtesa® (vibegron) – New indication

- On December 18, 2024, the FDA approved Sumitomo Pharma's Gemtesa (vibegron), for the treatment of **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 is also approved for the treatment of OAB with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

- The approval of Gemtesa for the new indication was based on a randomized, double-blind, placebo-controlled study in 1,105 male patients at least 45 years of age with OAB on pharmacological therapy (ie, treatment with an alpha blocker, with or without a 5-alpha reductase inhibitor) for BPH. Patients were randomized to Gemtesa or placebo for 24 weeks. The co-primary endpoints were change from baseline in the average daily number of micturitions and the average daily number of "need to urinate immediately" (urgency) episodes at week 12.

    — The change in average daily number of micturitions was -2.04 with Gemtesa vs. -1.30 with placebo (difference -0.74, 95% CI: -1.02, -0.46).
    — The change in average daily number of urgency episodes was -2.88 with Gemtesa vs. -1.93 with placebo (difference -0.95, 95% CI: -1.37, -0.54).

- The recommended dosage of Gemtesa is one 75 mg tablet orally, once daily with or without food.