Gemtesa® (vibegron) – New drug approval

- On December 23, 2020, Urovant Sciences announced the FDA approval of Gemtesa (vibegron), for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

- OAB is a common condition that occurs when the bladder muscle contracts involuntarily. Over 30 million Americans are estimated to suffer from bothersome symptoms of OAB.

- Gemtesa is a selective human beta-3 adrenergic receptor agonist. Activation of the beta-3 adrenergic receptor increases bladder capacity by relaxing the detrusor smooth muscle during bladder filling.

- The efficacy of Gemtesa was established in a 12-week, double-blind, randomized, placebo-controlled, and active-controlled study in 1,515 patients with OAB (urge urinary incontinence, urgency, and urinary frequency). The co-primary endpoints were change from baseline in average daily number of micturitions and average daily number of urge urinary incontinence (UUI) episodes at week 12.

    — The change from baseline at week 12 in the average daily number of micturitions was -1.8 and -1.3 for Gemtesa and placebo, respectively (difference of -0.5, 95% CI: -0.8, -0.2; $p < 0.001$).
    — The change from baseline at week 12 in the average daily number of UUI episodes was -2.0 and -1.4 for Gemtesa and placebo, respectively (difference of -0.6, 95% CI: -0.9, -0.3; $p < 0.0001$).

- A warning and precaution for Gemtesa is urinary retention.

- The most common adverse reactions (2%) with Gemtesa use were headache, urinary tract infection, nasopharyngitis, diarrhea, nausea, and upper respiratory tract infection.

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

- Urovant Sciences plans to launch Gemtesa late in the first quarter of 2021. Gemtesa will be available as a 75 mg tablet.