

Gemtesa® (vibegron) – New drug approval

- On December 23, 2020, <u>Urovant Sciences announced</u> the FDA approval of <u>Gemtesa (vibegron)</u>, 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.



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 $\mbox{RxNews}^{\mbox{\tiny @}}$ is published by the OptumRx Clinical Services Department.

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