GEMTESA® (vibegron)
Phase 3 EMPOWUR Trial
Concomitant Medications

GEMTESA® (vibegron) 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.[1] Please see accompanying full Prescribing Information.

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Summary

- The 12-week phase 3 trial demonstrated once-daily vibegron 75 mg provided statistically significant reductions in daily micturitions, urge urinary incontinence (UUI), episodes of urgency, and increased the volume of urine per micturition relative to placebo. Among adverse events (AEs) of clinical interest, the rates of hypertension, increased blood pressure, urinary tract infection and urinary retention were similar to placebo.[2]
    - AE incidence of hypertension (1.7% for vibegron and for placebo), blood pressure increase (0.7% for vibegron, 0.9% for placebo), urinary tract infection (5.0% for vibegron, 6.1% for placebo), urinary retention (0.4% for vibegron, 0.6% for placebo).

Phase 3 EMPOWUR Trial

This international, randomized, double-blind, placebo- and active-controlled study consisted of a 1- to 5-week screening period; a 28-day washout period; a 2-week single-blind (subject) placebo run-in period; a 12-week randomized, double-blind treatment period; and a 4-week follow-up safety evaluation.[1,2]

Exclusion Criteria – Concomitant Medications

Table 1 provides a listing of specific restrictions for concomitant therapy use during the study, with any necessary washout periods described.[3]

Use of other concomitant therapies listed below were also prohibited if the patient's dose had changed in the 4 weeks prior to the Baseline Visit or if the patient had planned to initiate or change any of these therapies during the study.[3]

- Tricyclic antidepressants or combinations.
- Alpha-1-antagonists, unless used for Benign Prostatic Hyperplasia (BPH) treatment, in which case, stable dosing for 3 months is required.
- Serotonin and/or norepinephrine reuptake inhibitors.
- Alpha-adrenergic agonists.
- Diuretic therapy.
- Inhaled anticholinergic.
- Regular use of phosphodiesterase type 5 (PDE 5) inhibitors.

Note: Occasional use of PDE 5 inhibitors (e.g., for the treatment of erectile dysfunction) was allowed throughout the study.

Table 1: Listing of Prohibited Drug Classes[3]

Class	Washout Period/Comments
Anticholinergics	Patient must discontinue use at least 28 days prior to beginning completion of the Screening Patient Voiding Diary and remain off this therapy during the study
Smooth muscle relaxants	Patient must discontinue use at least 28 days prior to beginning completion of the Screening Patient Voiding Diary and remain off this therapy during the study
Beta-2 adrenergic agonists used for the treatment of stress urinary incontinence	Patient must discontinue use at least 28 days prior to beginning completion of the Screening Patient Voiding Diary and remain off this therapy during the study
Systemic beta-2 adrenergic agonist	No washout period; patient must remain off this therapy during the study
Synthetic antidiuretics hormones	Patient must discontinue use at least 28 days prior to beginning completion of the Screening Patient Voiding Diary and remain off this therapy during the study
Beta-3 adrenergic agonists	Patient must discontinue use at least 28 days prior to beginning completion of the Screening Patient Voiding Diary and remain off this therapy during the study
Medications with a narrow therapeutic index	Patient must not have taken this therapy within 28 days prior to the Screening Visit and remain off this therapy during the study
Intradetrusor botulinum toxins	Patient must not have received an injection within 9 months prior to the Screening Visit and must not receive this therapy during the study

References

1. GEMTESA® [package insert]. Irvine, CA: Urovant Sciences, Inc; 2020
2. Staskin D, Frankel J, Varano S, et al. International phase III, randomized, double-blind, placebo and active controlled study to evaluate the safety and efficacy of vibegron in patients with symptoms of overactive bladder: EMPOWUR. *J Urol*. 2020;204:316-324. https://www.auajournals.org/doi/10.1097/JU.0000000000000807
3. Data on file (2019) Urovant Sciences. Clinical Study Report. An International Phase 3, Randomized, Double-Blind, Placebo- and Active (Tolterodine)-Controlled Multicenter Study to Evaluate the Safety and Efficacy of Vibegron in Patients with Symptoms of Overactive Bladder.