

Efficacy and Safety of Once-Daily Vibegron in Older Adults with Overactive Bladder

Subpopulation Analysis from the EMPOWUR Randomized, International, Phase III Trial

Urovant Sciences

NCT03492281

Overactive Bladder (OAB)

Overactive bladder (OAB) is prevalent among older adults (>45 years)¹.

Current drug treatments (anticholinergics) are rife with side-effects and are **not recommended**.

Vibegron (β 3-adrenergic agonist) was deemed safe and effective for OAB treatment (EMPOWUR)².



Does Vibegron treat OAB in geriatric adults?

Objective: assess the efficacy of daily 75 mg vibegron in treating OAB in geriatric adults (≥ 65 and ≥ 75 years).

12-week, randomized, double-blind, placebo- and active-control
(**4 mg tolterodine**).

Included geriatric adults (≥ 65 years) with at least 3 months of OAB.

Treatment groups are well-balanced

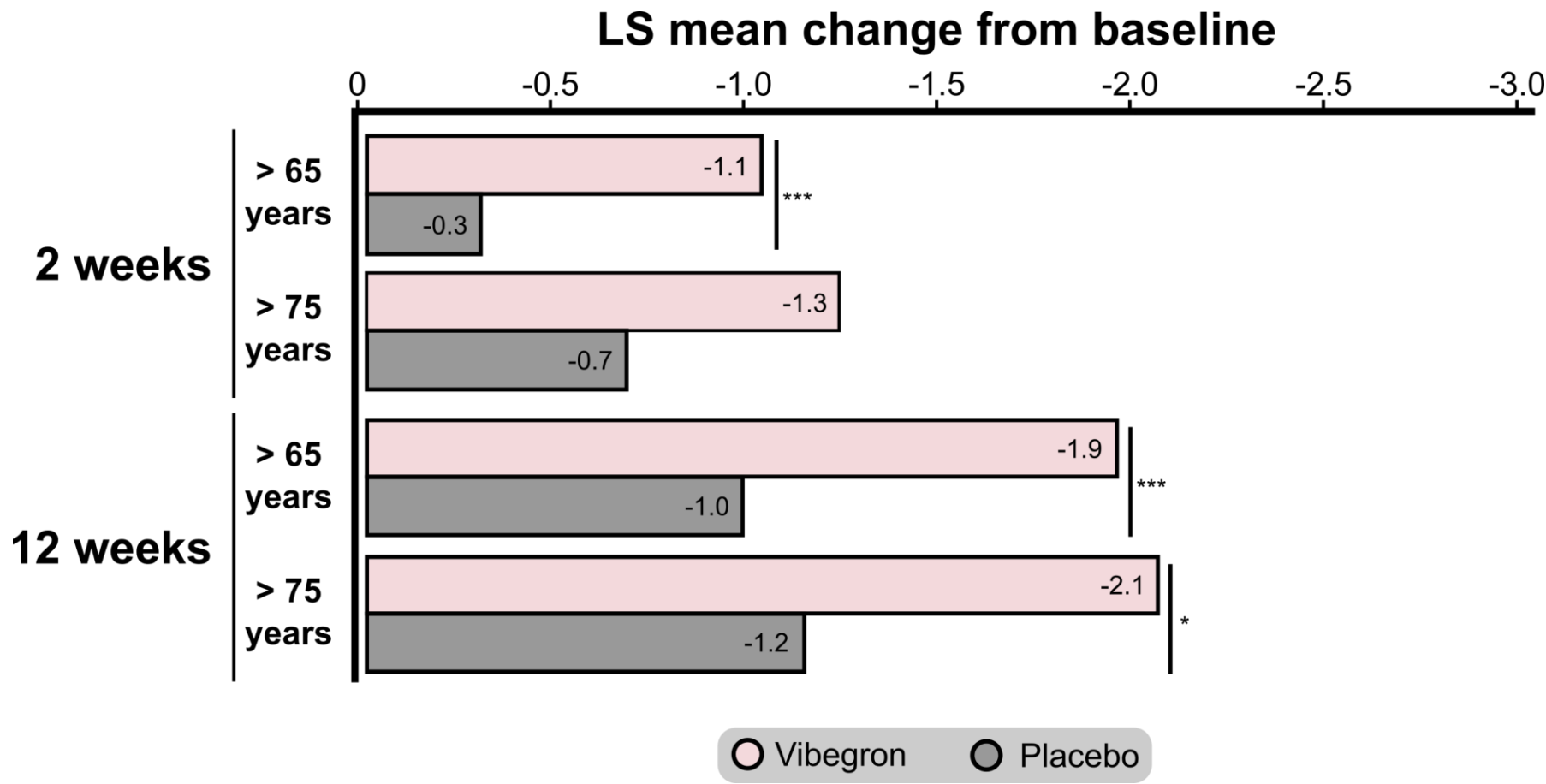
Primary endpoints: daily micturitions and urge urinary incontinence (UUI).

Secondary efficacy endpoints: daily urgency episodes.

Subgroup	Total	Vibegron	Placebo	Tolterodine
≥ 65 years	628	242	220	166
≥ 75 years	179	75	57	47

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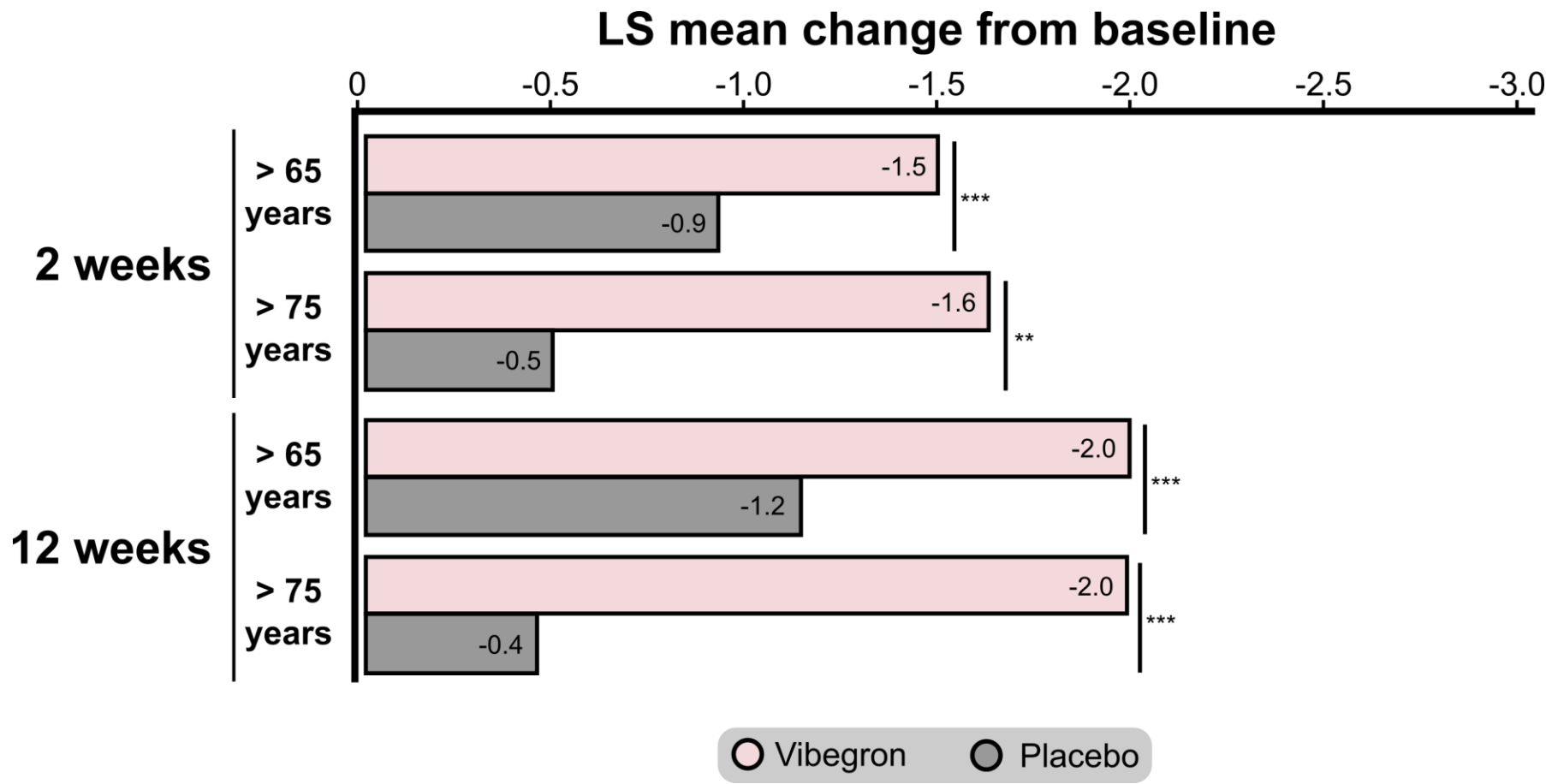
Vibegron reduced daily micturitions by week 2



(LS) least-squares, * $P < 0.05$, *** $P < 0.001$

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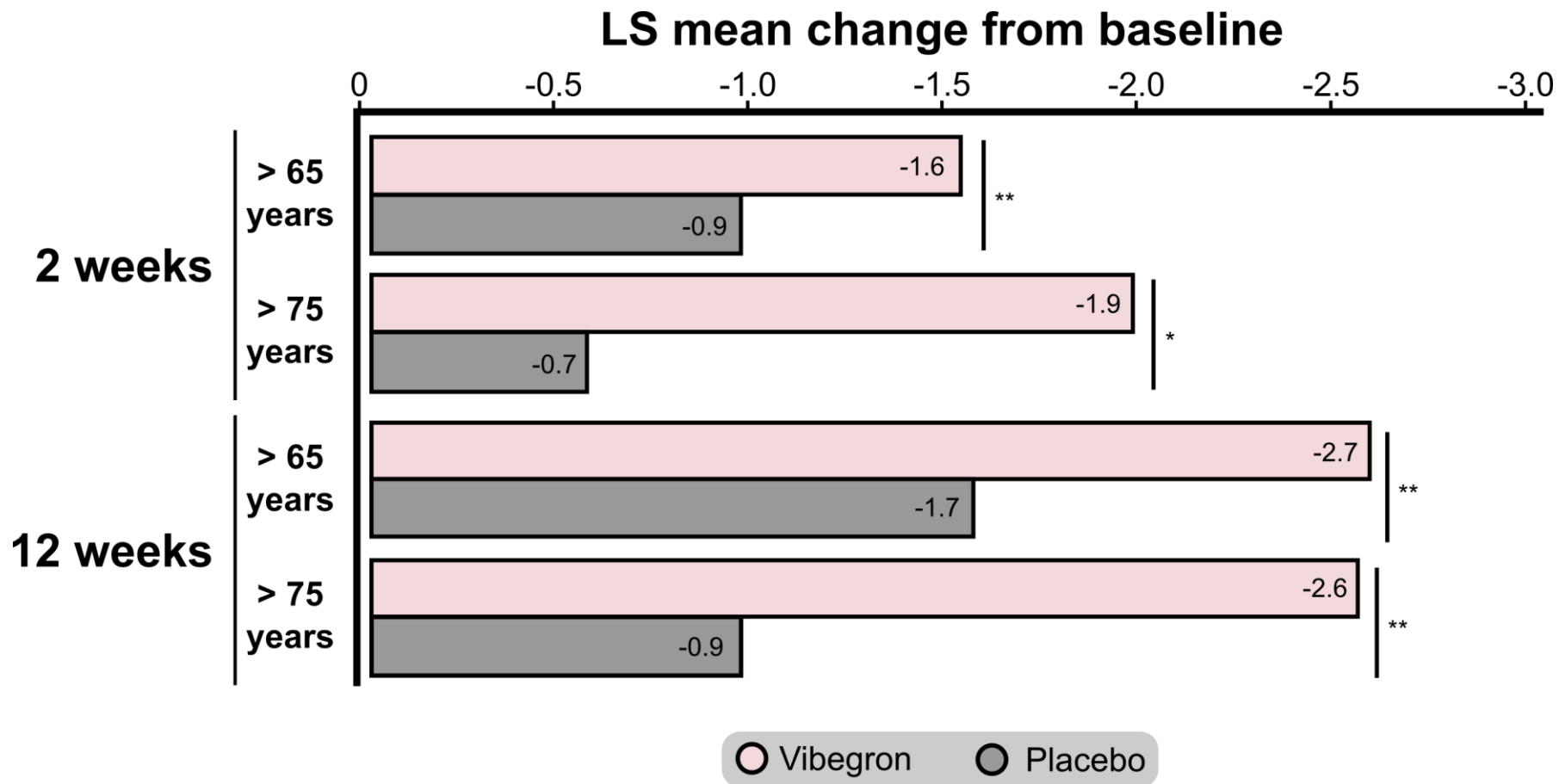
Vibegron demonstrates similar efficacy with UUI



(LS) least-squares, ** $P < 0.01$, *** $P < 0.001$

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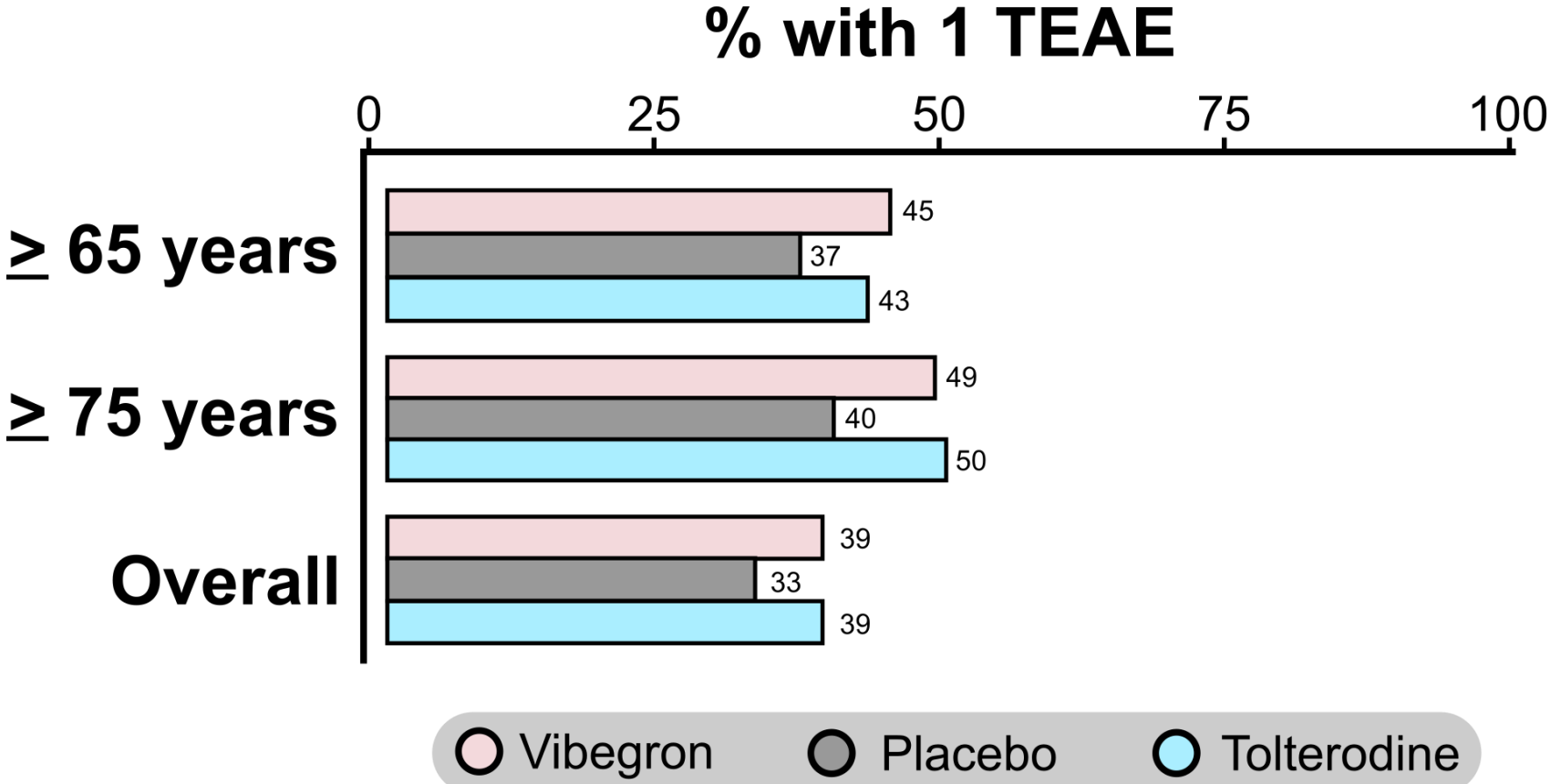
Urgency episodes were reduced across both age groups



(LS) least-squares, * $P < 0.05$, ** $P < 0.01$

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The safety profile is akin to the placebo and control



(TEAE) treatment-emergent adverse event

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Key points and takeaways

- 1** Once-daily **75 mg vibegron** provides OAB relief improvements across both coprimary endpoints.
- 2** Treatment with vibegron also demonstrated improvement with secondary efficacy endpoints.
- 3** Vibegron's safety profile is consistent with the overall population and the placebo.

References

1. Varano S, Staskin D, Frankel J, Shortino D, Jankowich R, Mudd PN. Efficacy and Safety of Once-Daily Vibegron for Treatment of Overactive Bladder in Patients Aged ≥ 65 and ≥ 75 Years: Subpopulation Analysis from the EMPOWUR Randomized, International, Phase III Study. *Drugs and Aging*. 2021;38(2):137-146. doi:10.1007/S40266-020-00829-Z/TABLES/4
2. Staskin D, Frankel J, Varano S, Shortino D, Jankowich R, Mudd PN. 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. *The Journal of Urology*. 2020;204(2):316-323. doi:10.1097/JU.0000000000000807