

UROVANT SCIENCES

EMPOWUR PHASE 3 RESULTS

March 2019

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This presentation contains forward-looking statements, including without limitation, statements related to: our plans to file for approval of vibegron with the FDA, and the timing of such filing and the likelihood of FDA approval; our ability to successfully develop Vibegron in the United States and other major markets, including meeting clinical endpoints and adequacy of clinical trial results; our ability to commence and complete new clinical trials, including for URO-902, as planned and on expected timelines; the commercial potential for Vibegron, including market size, reimbursement status, potential expanded indications and product differentiation relative to competitors; and the expected duration of patent protection. Forward-looking statements can be identified by "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words or other similar expressions or variations, although not all forward-looking statements contain these identifying words. Urovant cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements.

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EMPOWUR Phase 3 Topline Summary

- Strong efficacy results delivered with a once daily 75mg convenient dose
 - Vibegron achieved co-primary endpoints demonstrating statistically significant reduction in daily micturitions and daily urge urinary incontinence episodes (UUI), compared to placebo
 - At all measured timepoints, vibegron achieved numerically better efficacy than tolterodine, the active control in this study, which is a currently available OAB treatment
 - Statistical significance achieved for all seven key secondary endpoints, compared to placebo
- Rapid onset at two weeks in both co-primary endpoints and daily urgency episodes
 - Statistically significant efficacy was maintained at all timepoints measured through the end of the study
- Well tolerated with very few AEs >2% and greater than placebo
- No difference versus placebo in the reported AE of hypertension
- Potential best in class treatment option for OAB patients

EMPOWUR Results: Vibegron Demonstrated Strong Efficacy Across All OAB Endpoints

Week 12 LS Mean Change from Baseline (Placebo-Adjusted)

Endpoint	Vibegron	n	p-value	Tolterodine	n	p-value
UUI Episodes ¹	-0.6	383	<0.0001	-0.4	286	0.0123
Micturitions ¹	-0.5	492	<0.001	-0.3	378	0.0988
Urgency Episodes ²	-0.7	492	0.0020	-0.4	378	0.0648
Total Incontinence Episodes ²	-0.7	383	<0.0001	-0.5	286	0.0074
Volume Voided (ml) ²	21.2	490	<0.0001	13.3	375	<0.001
OAB-q Coping Score ²	3.6	512	0.0038	3.1	401	0.0212

1. Co-primary endpoint; 2. Key Secondary Endpoint; LS=Least Squares

VIBEGRON

POTENTIAL POINTS OF DIFFERENTIATION¹

	Vibegron ²	Mirabegron	ACH
Highly selective for human $\beta 3$ receptor ³	✓	✗	n/a
Rapid onset of efficacy at 2 weeks	✓	✗	✗
Potential efficacy claim for urgency ⁴	✓	✗	✗
Potential broader efficacy claims	✓	✗	✗
No CYP2D6 drug-drug interactions	✓	✗	Some
No QTc signal	✓	✗	✗
Single convenient crushable dose ⁵	✓	✗	✗
No known dementia risk ⁶	✓	✓	✗

1 Based on product labels, publicly available literature, and data on file

2 Based on clinical trials to date. Vibegron is in Phase 3 clinical development for OAB and has not been approved by the FDA or any other regulatory authority. All potential points of differentiation are subject to verification through further clinical development of vibegron and the review of the FDA

3 Based on in vitro data

4 Subject to approval by the FDA, including FDA approval of the inclusion of urgency data

5 Assuming successful result in planned relative bioavailability study or FDA acceptance of in vitro data

6 Gray et al. JAMA Intern Med. 2015



POPULATION

Women and men with OAB wet or dry



DURATION

12-week treatment period plus 40-week extension



KEY ENDPOINTS

Co-primary endpoints:

Change from baseline in daily number of (1) micturitions and (2) urge urinary incontinence episodes

Initiated:
1Q 18

Top-Line Data:
March 2019

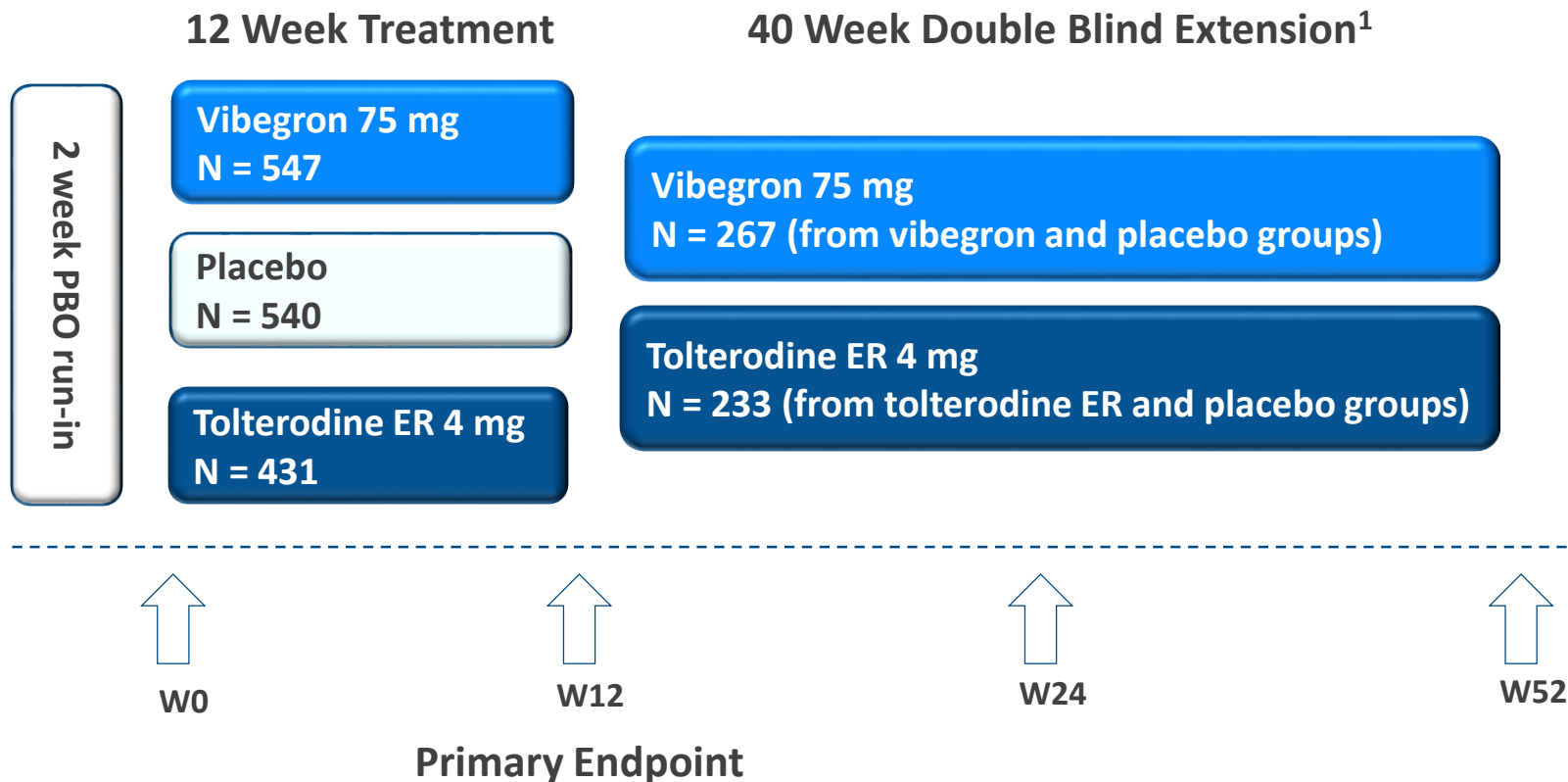


Table 14.1.1.3. Randomized Set
1 Numbers of patients reflect planned enrollment



Demographics and Disposition

EMPOWUR Demographics

	Placebo N=520	Vibegron N=526	Tolterodine N=417
Mean Age, in years (SD)	59.9 (13.33)	60.8 (13.30)	59.8 (13.19)
Subjects ≥ 65 yr, n (%)	220 (42.3)	242 (46.0)	166 (39.8)
Subjects ≥75 yr, n (%)	57 (11.0)	75 (14.3)	47 (11.3)
Female, n (%)	445 (85.6)	449 (85.4)	352 (84.4)
Male, n (%)	75 (14.4)	77 (14.6)	65 (15.6)
OAB Wet , n (%) (with incontinence)	405 (77.9)	403 (76.6)	319 (76.5)
OAB Dry, n (%) (without incontinence)	115 (22.1)	123 (23.4)	98 (23.5)
Region, n (%)	US: 463 (89.0) Non-US: 57 (11.0)	US: 472 (89.7) Non-US: 54 (10.3)	US: 376 (90.2) Non-US: 41 (9.8)

Table 14.1.3.1.2 , Full Analysis Set

EMPOWUR Subject Disposition

	Placebo N=540	Vibegron N=547	Tolterodine N=431
Randomized, n (%)	540 (100.0)	547 (100.0)	431 (100.0)
Completed 12 weeks of treatment, n (%)	486 (90.0)	502 (91.8)	385 (89.3)
Discontinued, n (%) – Due to AEs	54 (10.0) 6 (1.1)	45 (8.2) 8 (1.5)	46 (10.7) 13 (3.0)

Table 14.1.1.3, Randomized Set



Co-Primary Efficacy Results

Vibegron Met Both Co-primary Efficacy Endpoints

Highly Statistically Significant Reductions in Urge Urinary Incontinence and Micturitions

Urge Urinary Incontinence	Placebo	Vibegron	Tolterodine
Baseline Mean (n)	3.49 (405)	3.43 (403)	3.42 (319)
Change from BSL LS Mean (n)	-1.4 (372)	-2.0 (383)	-1.8 (286)
LS Mean Difference (95% CI)	-----	<u>Vibegron - Placebo</u> -0.6 (-0.9, -0.3)	<u>Tolterodine - Placebo</u> -0.4 (-0.7, -0.1)
P-Value		<0.0001	0.0123

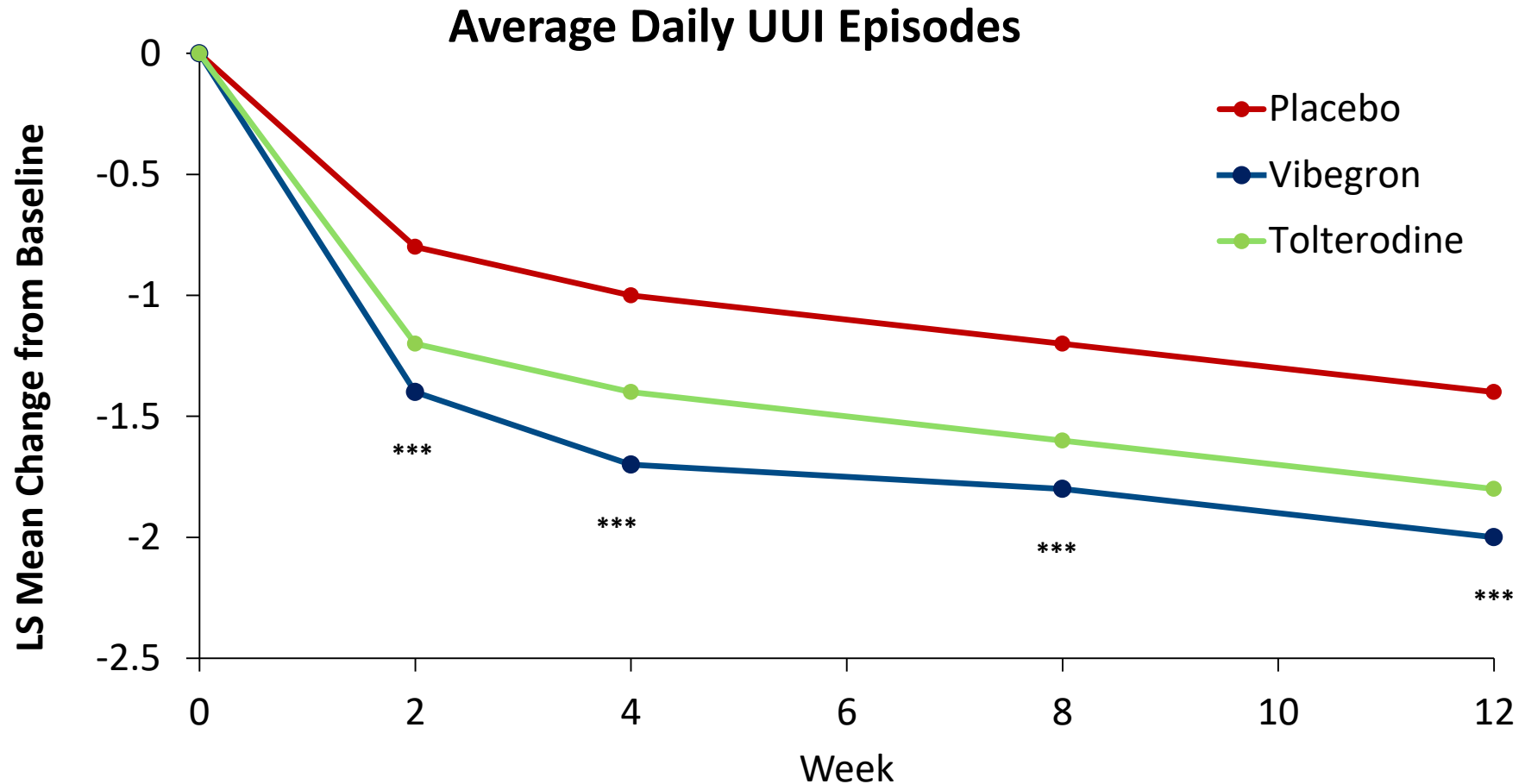
Table 14.2.2.1.2, Full Analysis Set for Incontinence, CFB Least squares mean at Week 12
Covariates included in the mixed model for repeated measures are study visit, sex, region, baseline number of UUI, and treatment by study visit interaction.

Micturitions	Placebo	Vibegron	Tolterodine
Baseline Mean (n)	11.75 (520)	11.31 (526)	11.48 (417)
Change from BSL LS Mean (n)	-1.3 (475)	-1.8 (492)	-1.6 (378)
LS Mean Difference (95% CI)	-----	<u>Vibegron - Placebo</u> -0.5 (-0.8, -0.2)	<u>Tolterodine - Placebo</u> -0.3 (-0.6, 0.1)
P-Value		<0.001	0.0988

Table 14.2.1.1.2, Full Analysis Set, CFB Least squares mean at Week 12
Covariates included in the mixed model for repeated measures are study visit, OAB type, sex, region, baseline number of micturitions, and treatment by study visit interaction.

Reduction in Urge Urinary Incontinence (UUI) Over Time

Statistically Significant Onset of Action at 2 Weeks



P-value is vibegron vs placebo
*P-value: ***<0.001*

Table 14.2.2.1.2, Full Analysis Set for Incontinence, CFB Least squares mean
Covariates included in the mixed model for repeated measures are study visit, sex, region, baseline number of UUI, and treatment by study visit interaction.

Reduction in Micturitions Over Time

Statistically Significant Onset of Action at 2 Weeks

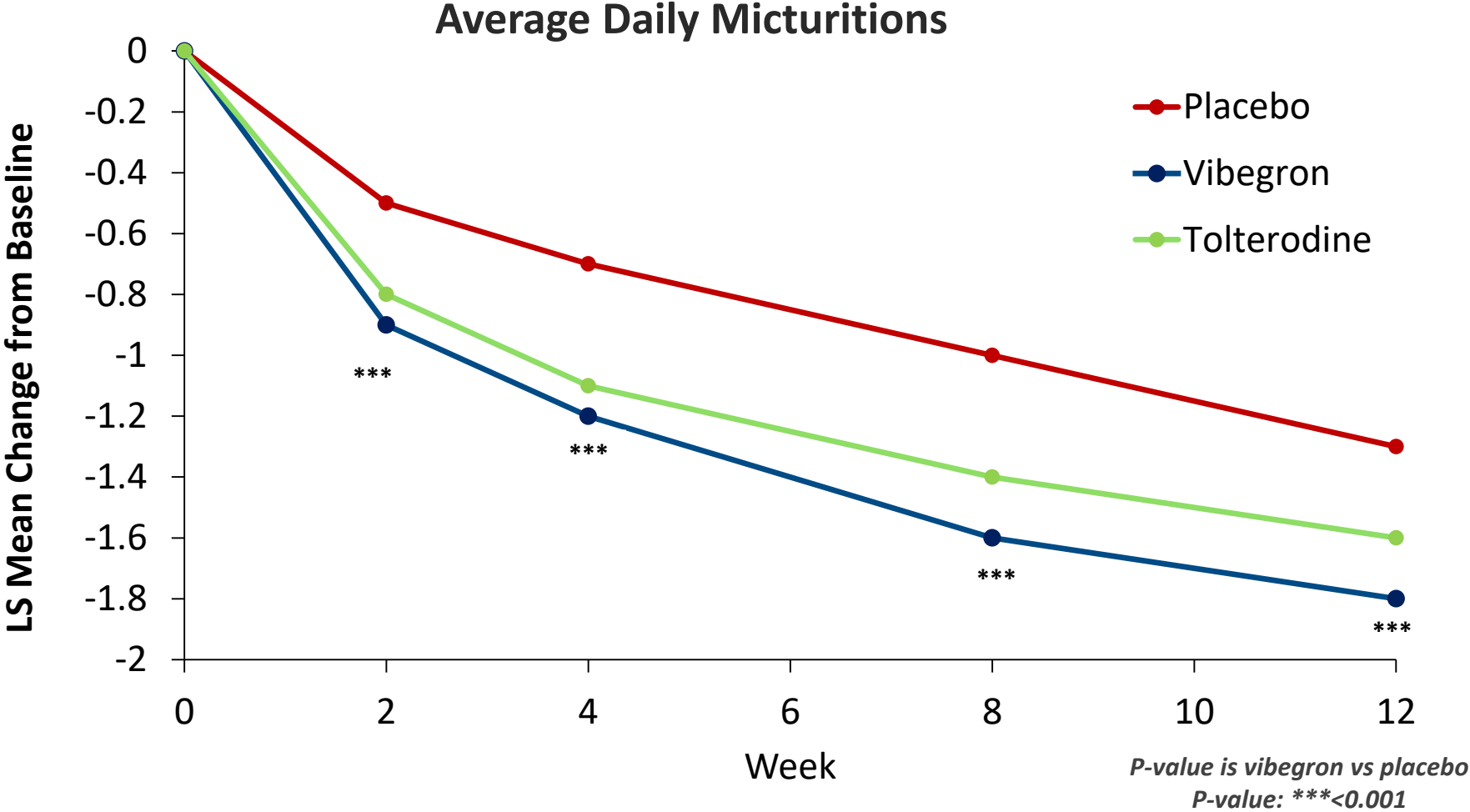


Table 14.2.1.1.2, Full Analysis Set, CFB Least squares mean
Covariates included in the mixed model for repeated measures are study visit, OAB type, sex, region, baseline number of micturitions, and treatment by study visit interaction.



Key Secondary Endpoints

Statistically Significant Reduction in Urgency Episodes

Urgency	Placebo N=520	Vibegron N=526	Tolterodine N=417
Baseline Mean (n)	8.13 (520)	8.11 (526)	7.92 (417)
Change from BSL LS Mean (n)	-2.0 (475)	-2.7 (492)	-2.5 (378)
LS Mean Difference (95% CI) P-Value	-----	<u>Vibegron – Placebo</u> -0.7 (-1.1, -0.2) 0.0020	<u>Tolterodine-Placebo</u> -0.4 (-0.9, 0.0) 0.0648

Table 14.2.3.1.2, Full Analysis Set, CFB Least squares mean at Week 12

Covariates included in the mixed model for repeated measures are study visit, OAB type, sex, region, baseline number of urgency episodes, and treatment by study visit interaction.

Reduction in Urgency Episodes Over Time

Statistically Significant Onset of Action at 2 Weeks

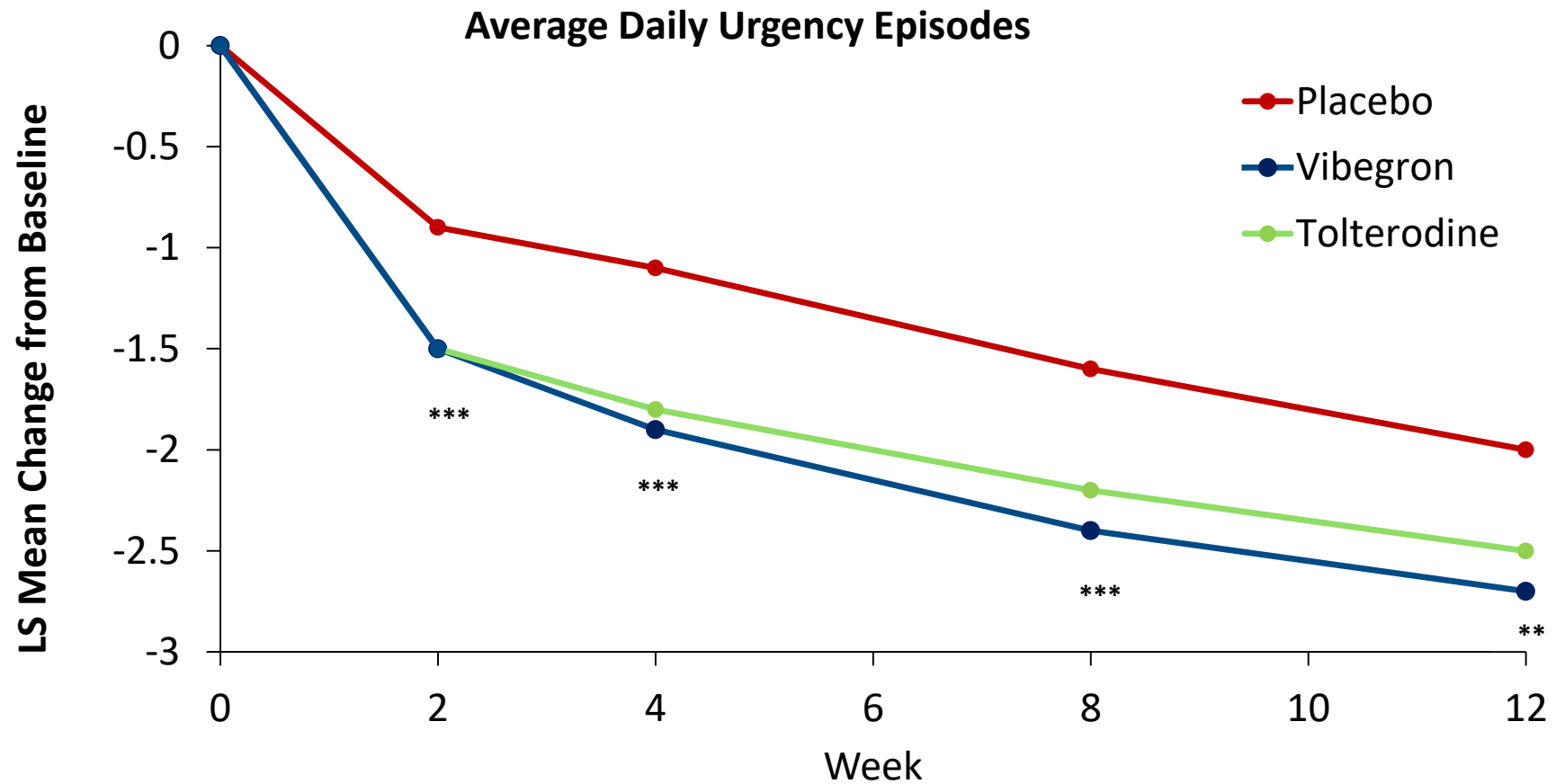
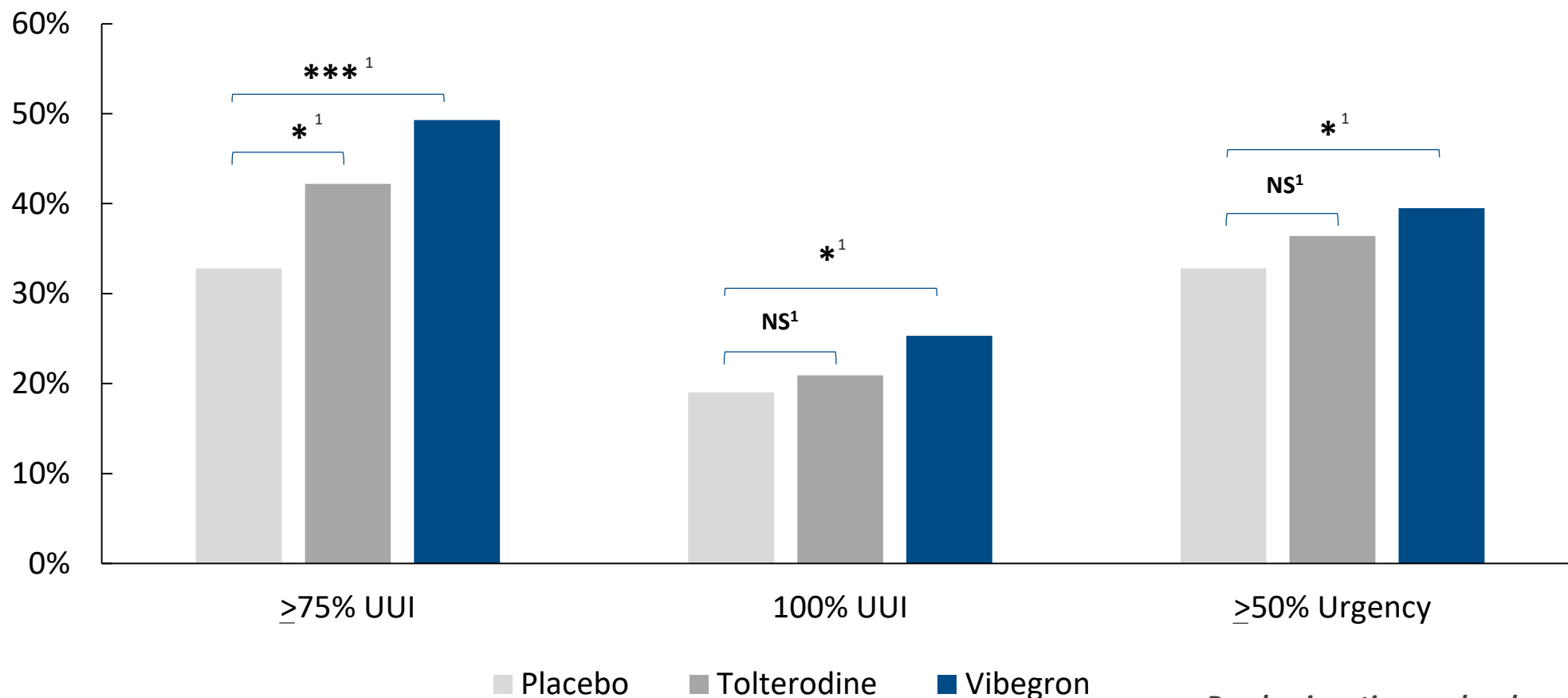


Table 14.2.3.1.2, Full Analysis Set, CFB Least squares mean
Covariates included in the mixed model for the repeated measures are study visit, OAB type, sex, region, baseline number of urgency episodes, and treatment by study visit interaction.

P-value is vibegron vs placebo
P-values: **<0.01, ***<0.001

UUI and Urgency Responders at Week 12

Percent of Responders with $\geq 75\%$ and 100% Reductions in UUI Episodes and $\geq 50\%$ Reduction in Urgency Episodes



P-value is active vs placebo
P-values: * <0.05 , ** <0.01 , *** <0.001

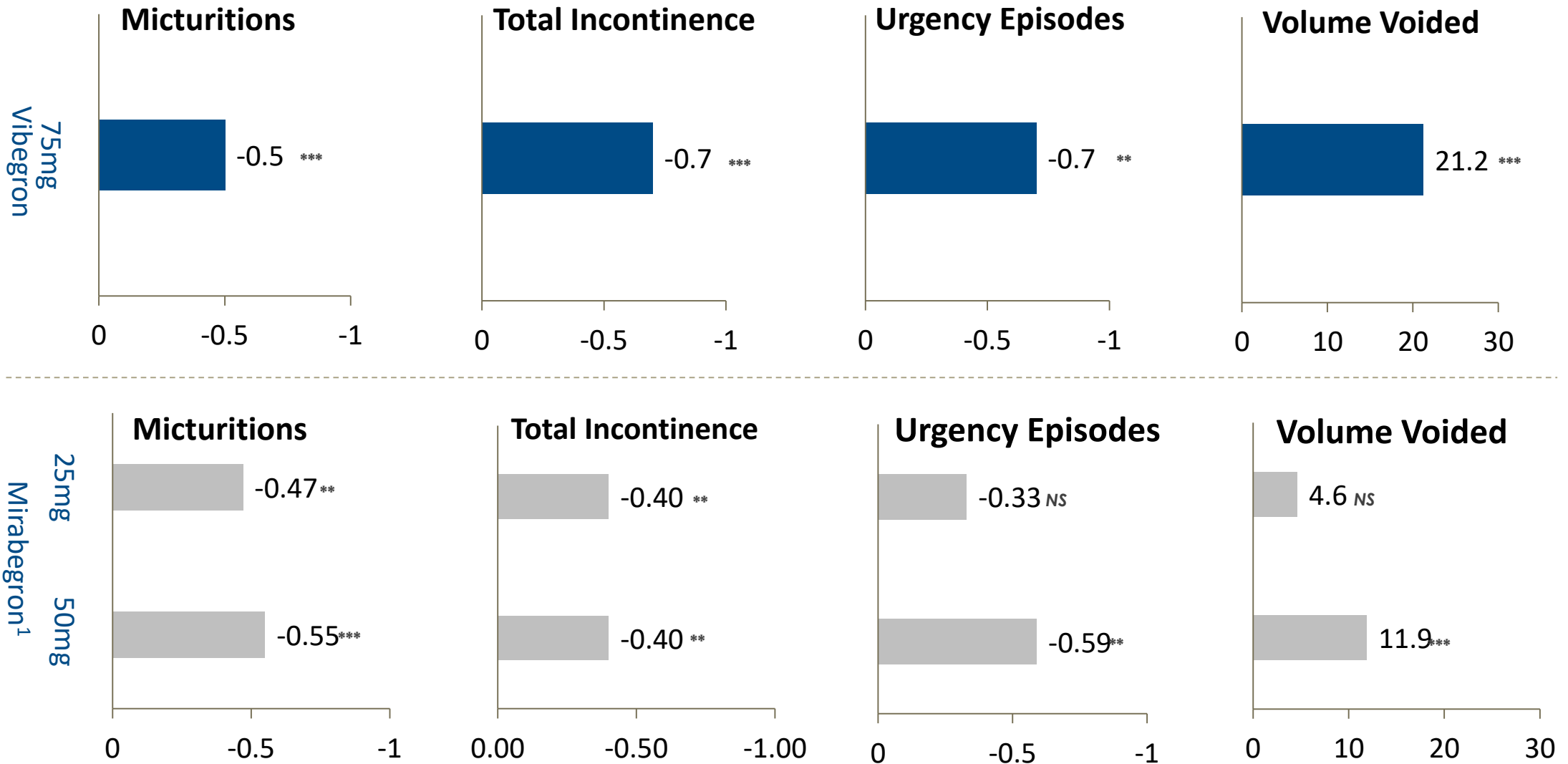
¹ p-values for the difference in proportions between active and placebo were calculated using the Cochran-Mantel-Haenszel risk difference estimate stratified by OAB Type (Wet vs Dry) and Sex (Female vs Male), with weights proposed by Greenland and Robins. MI has been used to impute values missing for any reason at the weeks analyzed. Adjusted proportions are presented.

Table 14.2.4.1.1 Full Analysis Set for Incontinence. 75% Reduction in UUI from Baseline at Week 12
 Table 14.2.5.1.1 Full Analysis Set for Incontinence. 100% Reduction in UUI from Baseline at Week 12
 Table 14.2.6.1.1 Full Analysis Set 50% Reduction in Urgency from Baseline at Week 12

VIBEGRON PHASE 3 AND MIRABEGRON PHASE 3 RESULTS

The below is not a head-to-head trial. These trials were conducted at different points in time using different trial designs.

Adjusted mean change from baseline to final visit (active – placebo)



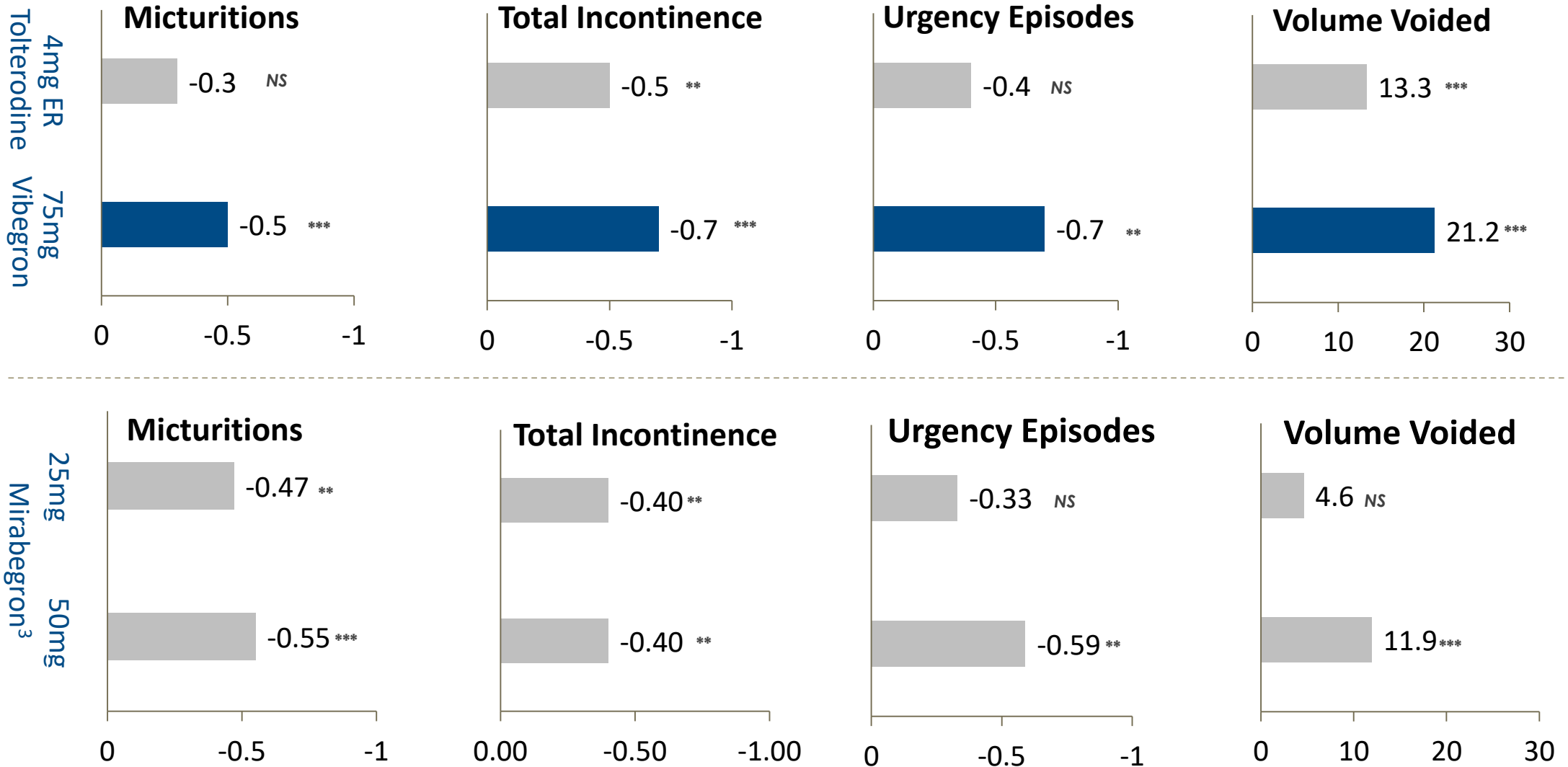
¹Data from trial '074, except for 50 mg micturitions, total incontinence, and volume voided which is averaged from trials '046, '047, and '074; trials '046 and '047 did not test the 25 mg dose. For averaged effect sizes, the highest level of significance is shown.

P-values: * < 0.05, ** < 0.01, *** < 0.001

VIBEGRON PHASE 3 AND MIRABEGRON PHASE 3 RESULTS

The below is not a head-to-head trial. These trials were conducted at different points in time using different trial designs.

Adjusted mean change from baseline to final visit (active – placebo)



¹Data from trial '074, except for 50 mg micturitions, total incontinence, and volume voided which is averaged from trials '046, '047, and '074; trials '046 and '047 did not test the 25 mg dose. For averaged effect sizes, the highest level of significance is shown.

P-values: *<0.05, **<0.01, ***<0.001

Vibegron 75mg EMPOWUR and Mirabegron 25mg/50mg CAPRICORN

The below is not a head-to-head trial. These trials were conducted at different points in time using different trial designs. All data are presented as change from baseline (active – placebo)

EMPOWUR

Endpoint (Week 12)	75 mg Vibegron
Micturitions	-0.5 (<0.001)
Urge Incontinence	-0.6 (<0.0001)
Total Incontinence	-0.7 (<0.0001)
Urgency	-0.7 (0.002)
Volume Voided	21.2 (<0.0001)
OAB-q Bother	-6.9 (<0.0001)
OAB-q Total	3.8 (<0.001)
Onset	
Micturitions	-0.5 (<0.001) Wk 2
Urge Incontinence	-0.6 (<0.0001) Wk 2
Total Incontinence	-0.7 (<0.0001) Wk 2

CAPRICORN¹

25mg Mirabegron	50mg Mirabegron
-0.47 (0.007)	-0.42 (0.015)
NS	Not reported
-0.40 (0.005)	-0.42 (0.001)
NS	-0.59 (0.007)
NS	12.4 (<0.001)
NS	-2.8 (0.028)
NS	NS
Onset	
NS	-0.37 (0.035) Wk 4
-0.36 (0.004) Wk 4	-0.39 (0.002) Wk 4
-0.34 (0.039) Wk 4	-0.51 (<0.001) Wk 4

1.Herschorn et al. Urology 82(2), 2013

*All statistical tests were predefined and vary by study and endpoint. Adjusted mean change from baseline to final visit (active – placebo). NS = not statistically significant.

Results are tabulated separately from two phase 3 studies: 25 and 50 mg mirabegron (CAPRICORN) and 75mg vibegron (EMPOWUR)



Safety and Tolerability

Summary Of Treatment Emergent Adverse Events

Safety population n (%)	Placebo N=540	Vibegron N=545	Tolterodine N=430
Patients with at least one treatment-emergent adverse event	180 (33.3)	211 (38.7)	166 (38.6)
Patients with at least one treatment-emergent serious AE	6 (1.1)	8 (1.5)	10 (2.3)
SAEs resulting in death	0	0	1 (0.2)
Hospitalization	6 (1.1)	7 (1.3)	8 (1.9)
Other serious criteria	0	2 (0.4)	2 (0.5)
SAEs considered treatment-related by the investigator	0	2 (0.4)	0

Table 14.3.1.1, Safety Analysis Set
 SAE= Serious Adverse Event
 TEAE= Treatment Emergent Adverse Event

Most Common Key Adverse Events

Vibegron >2% and > Placebo

AE term n (%)	Placebo N=540	Vibegron N=545	Tolterodine N=430
Headache	13 (2.4)	22 (4.0)	11 (2.6)
Nasopharyngitis	9 (1.7)	15 (2.8)	11 (2.6)
Diarrhea	6 (1.1)	12 (2.2)	9 (2.1)
Nausea	6 (1.1)	12 (2.2)	5 (1.2)

Table 14.3.1.15, Safety Analysis Set. Represents number of patients.

Selected Key Adverse Events

AE term n (%)	Placebo N=540	Vibegron N=545	Tolterodine N=430
Hypertension	9 (1.7)	9 (1.7)	11 (2.6)
Blood pressure increased	5 (0.9)	4 (0.7)	8 (1.9)
Tachycardia	0	0	1 (0.2)
Hypotension	1 (0.2)	1 (0.2)	1 (0.2)
Dizziness	6 (1.1)	5 (0.9)	4 (0.9)
Urinary tract infection	33 (6.1)	27 (5.0)	25 (5.8)
Urinary retention	2 (0.4)	3 (0.6)	3 (0.7)
Dry mouth	5 (0.9)	9 (1.7)	28 (6.5)
Constipation	7 (1.3)	9 (1.7)	6 (1.4)
Fatigue	5 (0.9)	2 (0.4)	6 (1.4)

Table 14.3.1.2 Safety Analysis Set. Represents number of patients.

Vibegron is a Potential Best in Class Treatment Option for OAB Patients

- Strong efficacy results delivered with a once daily 75mg convenient dose
 - Vibegron achieved co-primary endpoints demonstrating statistically significant reduction in daily micturitions and daily urge urinary incontinence episodes (UUI), compared to placebo
 - At all measured timepoints, vibegron achieved numerically better efficacy than tolterodine, the active control in this study, which is a currently available OAB treatment
 - Statistical significance achieved for all seven key secondary endpoints, compared to placebo
- Rapid onset at two weeks in both co-primary endpoints and daily urgency episodes
 - Statistically significant efficacy was maintained at all timepoints measured through the end of the study
- Well tolerated with very few AEs >2% and greater than placebo
- No difference versus placebo in the reported AE of hypertension
- Potential best in class treatment option for OAB patients

Next Steps

- Presentation of the EMPOWUR results at the American Urological Association Annual Meeting in Chicago on Sunday, May 5th
- Long term extension study results expected in the Fall 2019
- Ambulatory blood pressure study results expected in Summer 2019
- Full publication of the manuscript planned for 2020
- Urovant intends to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) by early 2020



Backup

SAE Information - Deaths

SAE terms- (SAE criteria)	Age	Gender	Treatment group	Assessment by investigator
Stroke, sepsis, urinary tract infection (Hospitalization / death)	75 years	Female	Tolterodine	Not related

Table 14.3.2.1 Safety Analysis Set
Table 14.3.2.2 Safety Analysis Set

Reduction in Total Incontinence

Total Incontinence	Placebo N=405	Vibegron N=403	Tolterodine N=319
Baseline Daily Episodes, Mean (SD)	4.17 (3.823)	4.14 (3.631)	4.06 (3.071)
Change from baseline, n	372	383	286
LS Mean (SE)	-1.6 (0.15)	-2.3 (0.15)	-2.0 (0.16)
95% CI	-1.9, -1.3	-2.6, -2.0	-2.4, -1.7
Active – Placebo			
LS Mean Difference (SE)	-----	-0.7 (0.16)	-0.5 (0.17)
95% CI		-1.0, -0.4	-0.8, -0.1
P-Value		<0.0001	0.0074

Table 14.2.7.1.2 Full Analysis Set for Incontinence CFB Least squares mean at Week 12.
Covariates included in the mixed model for repeated measures are study visit, sex, region, baseline number of total incontinence episodes and treatment by study visit interaction.

Improvement in OAB-q Coping Score

OAB-q Coping	Placebo N=520	Vibegron N=526	Tolterodine N=417
Baseline, n	518	524	417
Mean (SD)	58.77 (27.169)	57.60 (28.054)	59.88 (26.470)
Change from baseline, n	504	512	401
LS Mean (SE)	12.9 (1.32)	16.5 (1.31)	15.9 (1.39)
95% CI	10.3, 15.5	13.9, 19.1	13.2, 18.7
Active – Placebo			
LS Mean Difference (SE)	-----	3.6 (1.24)	3.1 (1.32)
95% CI		1.2, 6.0	0.5, 5.6
P-Value		0.0038	0.0212

Table 14.2.8.1.2. Full Analysis Set. CFB Least squares mean at Week 12.

Higher scores correspond to a higher quality of life on the OAB-q Coping Score.

Covariates included in the mixed model for repeated measures are study visit, OAB type, sex, region, baseline OAB-q coping score and treatment by study visit interaction.

Increase in Volume Voided Per Micturition

Volume Voided (per micturition)	Placebo N=520	Vibegron N=526	Tolterodine N=417
Baseline n, Volume Voided mL (SD)	514 148.3 (60.67)	524 155.4 (63.07)	415 147.0 (60.79)
Change from baseline, n LS Mean (SE) 95% CI	478 2.2 (3.28) -4.2, 8.7	490 23.5 (3.26) 17.1, 29.9	375 15.5 (3.52) 8.6, 22.4
Active – Placebo LS Mean Difference (SE) 95% CI P-Value	-----	21.2 (3.52) 14.3, 28.1 <0.0001	13.3 (3.76) 5.9, 20.7 <0.001

Table 14.2.9.1.2, Full Analysis Set, CFB Least squares mean at Week 12.