111: Vesomni Improves Quality of Life in Men With Lower Urinary Tract Symptoms in Routine Clinical Practice in Europe

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INTRODUCTION

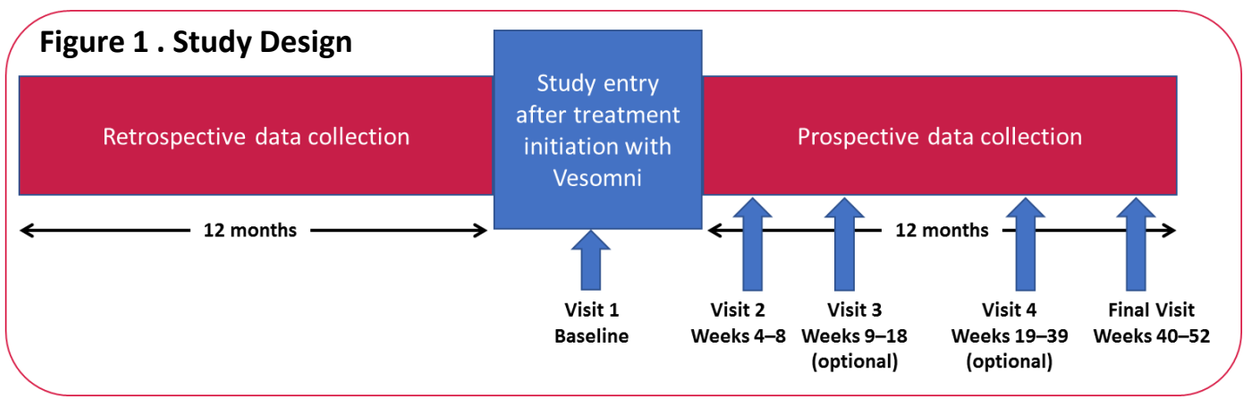
- Nearly two-thirds of men with storage and voiding LUTS do not adequately respond to α-blocker monotherapy and may benefit from add-on therapy with an antimuscarinic agent to improve residual storage symptoms[1]
- Vesomni™/Urizia™/Volutsa™ is a fixed-dose combination tablet of 6 mg solifenacin and 0.4 mg tamsulosin for the treatment of moderate-to-severe LUTS associated with benign prostatic hyperplasia (BPH) in patients who do not respond to monotherapy[2]
- EUROPA evaluated the impact of Vesomni on quality of life (QoL) and treatment satisfaction (TS) in men with LUTS/BPH who were not adequately responding to monotherapy in routine clinical practice

METHODS

Study design

- Prospective, non-interventional study (**Figure 1**) conducted at 48 sites in six European countries (Belgium, Czech Republic, Portugal, Slovenia, Spain, United Kingdom)
- Participants were men with LUTS/BPH who were not adequately responding to monotherapy with an α-blocker and/or 5α-reductase inhibitor and were prescribed Vesomni once daily in routine clinical practice

Figure 1 . Study Design



Endpoints

- Primary endpoint was the change from baseline in QoL assessed by the Overactive Bladder Questionnaire (OAB-q) symptom bother subscale score
- Secondary outcomes included changes from baseline in
  - OAB-q health-related QoL (HRQoL) total score and concern, coping, sleep, and social interaction subscale scores (0–100 score)
  - Treatment satisfaction-visual analogue scale (TS-VAS, 0–100 score)
  - Symptom severity via IPSS (0–35 score) and IPSS QoL (0–6 score)
  - Health status via the EuroQoL-Visual Analogue Scale (EQ-VAS, 0–100 score) component of the EQ-5D-5L
  - Treatment persistence (proportion of patients who remained on Vesomni)
- Safety was assessed by monitoring treatment-emergent adverse events (TEAEs)
- Data were captured on an electronic Patient Reported Outcome questionnaire

Statistical Analysis

- Analyses of endpoints were conducted on patients with baseline and ≥1 post-baseline OAB-q assessments (full analysis set [FAS])
- Safety analysis was conducted on patients who received ≥1 dose of Vesomni (safety analysis set [SAF])
- Analysis of covariance (ANCOVA) was used to assess changes from baseline for the OAB-q symptom bother subscale score with baseline scores as a covariate and baseline incontinence and prescription status as fixed factors
- Improvements of ≥10 points in any OAB-q subscale score, ≥3 points in total IPSS, and ≥0.5 points in IPSS-QoL were considered clinically meaningful [3,4]

RESULTS

Patient disposition

- Of 589 enrolled patients, 575 (97.6%) and 493 (83.7%) comprised the SAF and FAS
- 91 (15.8%; SAF) and 48 (9.7%; FAS) patients discontinued the study
- Demographics and baseline characteristics are reported in **Table 1**

Table 1 . Demographics and Baseline Characteristics

Parameter	FAS (n=493)
Age (years)	65.0 (10.4)
Caucasian race, n (%)	453 (91.9)
BMI (kg/m²)	28.39 (4.08)
Post-void residual volume (mL)[a]	36.4 (50.3)
Prostate size (mL)[b]	36.3 (16.8)
Prostate size ≥40 mL	167 (45.5%)
IPSS Total[c]	15.7 (6.3)
IPSS Total group	
0–7	41 (8.4%)
8–19	316 (64.8%)
20–35	128 (26.2%)
IPSS Storage[d]	8.0 (3.1)
IPSS Voiding[e]	7.7 (4.6)
OAB-q Symptom Bother score[f]	42.3 (17.6)
Prescription status	
Add-on[g]	74 (16.9%)
Switched[h]	363 (82.7%)
Combination[i]	2 (0.5%)
≥1 incontinence episode before baseline	138 (31.7%)

Data are presented as mean (SD) unless otherwise noted.
[a]Data from 184 patients; [b]Data from 367 patients; [c,d,e]Data from 485 patients; [f]Data from 493 patients; [g]Patients who had Vesomni added to their original monotherapy with an α-blocker or 5-ARI; [h]Patients who were switched to Vesomni from their original monotherapy with an α-blocker or 5-ARI; [i]Patients who had Vesomni added to their original treatment with an α -blocker and 5-ARI monotherapy.
Abbreviations: BMI, body mass index; IPSS, International Prostate Symptom Score; OAB-q, Overactive Bladder Questionnaire; SD, standard deviation; 5-ARI, 5-alpha-reductase inhibitor.

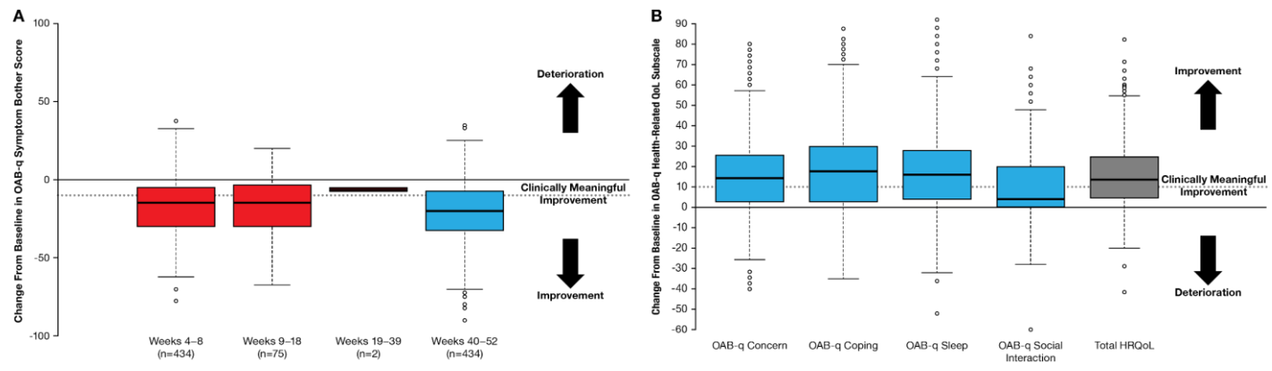
Primary Endpoint

- Clinically meaningful (≥10 points) changes in OAB-q symptom bother score were observed at Weeks 4–8, Weeks 9–18, and Weeks 40–52 (**Figure 2A**)
- 84.6% of patients achieved clinically meaningful improvements at Weeks 40−52
- The adjusted least squares mean (95% CI) changes from baseline in OAB-q symptom bother subscale scores were −16.40 (−24.31 to −8.49) at Weeks 4−8 and −19.59 (−28.26 to −10.92) at Weeks 40–52 (ANCOVA)

Secondary Endpoints

- Clinically meaningful (≥10 points) improvements were observed at Weeks 40−52 for the OAB-q HRQoL total score and subscales of concern, coping, and sleep (**Figure 2B**)
- The least squares mean (95% CI) change from baseline to Weeks 40−52 was 15.02 (7.35, 22.69) for concern, 19.37 (10.86, 27.89) for coping, 18.65 (7.44, 29.86) for sleep, 9.85 (3.90, 15.81) for social interaction, and 16.09 (9.07, 23.11) for OAB-q HRQoL total score (ANCOVA analysis)
- At Weeks 40–52, clinically meaningful improvements in OAB-q HRQoL total score and in the concern, coping, sleep, and social interaction subscale scores were observed in 65.7%, 60.8%, 67.3%, 68.9%, and 40.3% of patients, respectively

Figure 2. OAB-q Symptom Bother Subscale Scores (A) and OAB-q HRQoL Total and Subscale Scores at End of Study (B)

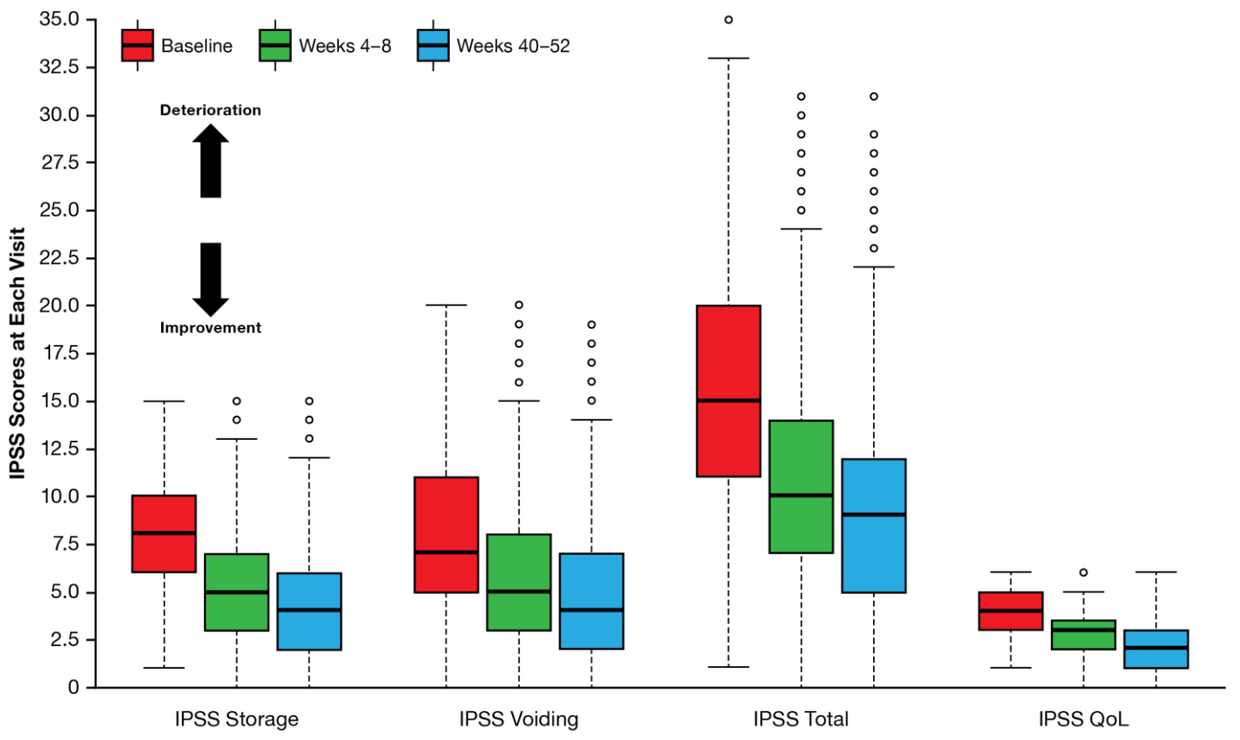


- TS-VAS and health status per EQ-VAS improved by Weeks 4−8 and through Week 40−52 (**Table 2**); adjusted mean (95% CI) changes from baseline for TS-VAS and EQ-VAS were 12.85 (−3.06, 28.77) and 4.96 (−4.19, 14.11), respectively, at Weeks 4−8; and 37.76 (22.31, 53.20) and 7.24 (−1.24, 15.72), respectively, at Weeks 40−52 (ANCOVA)
- Clinically meaningful (≥3 points) improvements were observed in total IPSS, IPSS Storage, and IPSS-QoL (≥0.5 points) (**Figure 3**)
- 380 (77.1%) patients remained on Vesomni treatment until the end of the study

Table 2 . Treatment Satisfaction and EQ-VAS Scores

Time Point	N	Mean (SD)	Change From Baseline	N	Mean (SD)	Change From Baseline
Treatment satisfaction (TS-VAS)				**Health Status (EQ-VAS)**		
Baseline	484	42.0 (28.0)	-	483	66.3 (17.5)	-
Weeks 4−8	415	64.9 (24.9)	22.8 (34.9)	414	72.7 (15.6)	6.0 (17.4)
Weeks 40−52	425	72.0 (24.0)	30.5 (34.3)	422	75.9 (14.1)	9.5 (17.9)

Figure 3. IPSS at Each Visit



Safety/Tolerability

- 383 TEAEs were reported in 195/575 (33.9%) patients; 34 serious TEAEs were reported in 25/575 (4.3%) patients
- 219 TEAEs that were possibly related to Vesomni were reported in 133/575 (23.1%) patients; 3 serious Vesomni-related TEAEs were reported in 3/575 (0.5%) patients
  - The most common Vesomni-related TEAE was dry mouth (n=41, 7.1%)
  - The proportion of patients who reported mild, moderate, and severe Vesomni-related TEAEs was 16%, 5.9%, and 1.2%, respectively
- Four cases of urinary retention occurred; none were classified as acute
- Four deaths were reported, none of which were related to Vesomni
- 3.1% (18/575) of patients reported lack of improvement of LUTS with Vesomni

CONCLUSIONS

- Vesomni yielded clinically meaningful improvements in QoL, treatment satisfaction, health status, and symptom severity in patients with LUTS/BPH in a real-world setting
  - Scores for the OAB-q symptom bother (the primary endpoint), OAB-q HRQoL total and subscales, TS-VAS, EQ-VAS and IPSS improved throughout the study
  - Notably, over 80% of patients achieved a clinically meaningful (≥10 points) improvement in OAB-q symptom bother score
- Vesomni was well-tolerated; no cases of acute urinary retention were reported
- Treatment persistence associated with Vesomni was high (77.1%)
- The results from EUROPA are similar to those previously reported in clinical trials of Vesomni and support the use of Vesomni in clinical practice in men with LUTS/BPH who do not adequately respond to monotherapy

REFERENCES

1. Lee HN, Lee KS, Kim JC, et al. *Int J Clin Pract*. 2015;69(4):444-453.
2. Vesomni™/Urizia™/Volutsa™. Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/medicine/28535/. Accessed 23 April, 2018.
3. Barry MJ, Williford WO, Chang Y, et al. *J Urol*. 1995;154(5):1770-1774.
4. Coyne KS, Matza LS, Thompson CL, Kopp ZS, Khullar V. *J Urol*. 2006;176(2):627-632.

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