### RESULTS

**Patient disposition**
- Of 589 enrolled patients, 575 (97.6%) and 493 (83.7%) comprised the SAF and FAS populations, respectively.
- 111 patients discontinued the study.
- Demographics and baseline characteristics are reported in Table 1.

**Endpoints**
- **Primary endpoint:** the change from baseline in QoL, as assessed by the Incontinence Quality of Life (IQoL) symptom bother subscale score.
- **Secondary endpoints** included changes from baseline in:
  - OAB symptom bother subscale score
  - Treatment satisfaction
  - Health status via the IPSS (0–35 score) and IPSS QoL (0–6 score)
- 484 participants were included for the efficacy analysis (48.0% data available for efficacy).

**Safety and tolerability**
- **Adverse events:** 383/575 (66.9%) patients reported at least 1 adverse event.
- **Serious adverse events:** 249/575 (43.9%) patients reported at least 1 serious adverse event.
- **Deaths:** 4 deaths were reported, none of which were related to Vesomni.
- The most common adverse events were:
  - Urinary tract infection (7.9%)
  - Bladder spasms (4.9%)
- The most common drug-related TEAE was dry mouth (7.1%)
- The primary endpoint was met, with clinically meaningful improvements of ≥10 points in any OAB symptom bother subscale score, and in the IPSS total score and subscales.

**Conclusions**
- Vesomni yielded clinically meaningful improvements in QoL, treatment satisfaction, health status, and symptom severity in patients with LUTS/BPH in a real-world clinical practice setting.
- Scores for the OAB-symptom bother (the primary endpoint), OAB-HRQoL total and subscales, TS-VAS, EQ-5D, and IPSS improved throughout the study.
- Four cases of urinary retention occurred; none were classified as acute.
- Four deaths were reported, none of which were related to Vesomni.

### METHODS

**Study design**
- Prospective, non-interventional study (Figure 1) conducted at 48 sites in six European countries:
  - Belgium, Czech Republic, Portugal, Spain, and Switzerland.
- Participants were men with LUTS/BPH who do not adequately respond to monotherapy with an α-blocker and/or 5α-reductase inhibitor.
- Prescribed Vesomni once daily in routine clinical practice.

**Data collection**
- Monitoring, data analysis, and electronic patient reported outcome management.
- The results from EUROPA are similar to those previously reported in clinical trials.

**Statistical analysis**
- Analyses of endpoints were conducted on patients with baseline and ≥1 post-baseline OAB-symptoms assessments (full analysis set [FAS]).

**Results**
- Clinically meaningful (≥10 points) improvements were observed at Weeks 40–52 for OAB-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 (13.55, 16.48) for concern, 19.37 (17.03, 21.71) for coping, and 8.00 (5.73, 10.27) for sleep.
- Patients who received ≤10 points in any OAB symptom bother subscale score, ≥3 points in total IPSS, and ≥5 points in IPSS-QoL were considered clinically meaningful responders.
- Endpoints were met for the OAB-symptom bother (the primary endpoint), OAB-HRQoL total and subscales, TS-VAS, EQ-5D, and IPSS improved throughout the study.

**Conclusions**
- Vesomni yielded clinically meaningful improvements in QoL, treatment satisfaction, health status, and symptom severity in patients with LUTS/BPH in a real-world clinical practice setting.
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