**METHODS**

### STUDY DESIGN

- Phase III, randomized, double-blind, parallel-design, placebo-controlled trial conducted at 8 sites in 4 countries (United States, Austria, Belgium, and Italy).

- Eligible patients were men ≥40 years old with BPH-LUTS (confirmed diagnosis) for ≥6 months, IPSS total score ≥7, and a peak urinary flow rate (Qmax) that was ≤15 mL/sec.

- Study candidates were excluded from participation if they exhibited any of the following:
  - RI in the prostate peripheral zone and bladder neck.
  - Color pixel intensity (CPI) in the prostate transition zone, prostate peripheral zone, and bladder neck.

### EFFICACY AND SAFETY MEASURES

- **TURSUS performed prior to randomization (baseline)** and at 4 and 8 weeks after randomization.

- All images were stored digitally and sent for central analysis.

- Computer-assisted quantification of pixel intensity was performed to calculate CPI within a standard 1-cm² region of interest.

- **Safety was assessed by collection of adverse events.**

### STATISTICAL ANALYSES

- A total of 96 subjects was estimated to provide 80% power to detect an adjusted mean treatment difference in RI of 0.07 (assuming a standard deviation of 0.12) using a 2-sided significance level of 0.05.

- Efficacy analyses utilized results from patients who were randomized to study treatment, received at least 1 dose of study drug, and who had a baseline and at least 1 postbaseline measurement.

- Safety analyses utilized results from all randomized patients according to the treatment to which they were assigned.

- A mixed-effects model for repeated measures (MMRM) analysis—utilizing treatment, region, visit, and treatment-by-visit interaction as fixed effects, baseline as a covariate, and patient as a random effect—was used for efficacy assessments (RI and CPI). Unstructured covariance was used to estimate within-patient serial correlation.

- Because baseline prostate RI was lower than expected, posthoc analyses of baseline-to-endpoints changes in prostate transition zone RI categorized by baseline RI subgroup (≤10 mL/sec versus >10 mL/sec) were conducted using analysis of covariance models with terms for treatment, region, RI baseline category, and RI baseline-category-by-treatment interaction, and adjusted for baseline prostate RI.

- **P-values were considered to be significant at the 5% level; confidence limits were expressed as 95% confidence intervals (CIs).**

### LIMITATIONS

- Despite adoption of standardized procedures across sites, variability in exam and imaging techniques may have influenced the ability to detect treatment differences that could not be completely overcome by central reading.

- Use of the same type of ultrasound machine across the sites was not practical or feasible in this multinational study.

- Limited sensitivity of the ultrasound may have precluded detection of smaller changes in flow with lower, daily doses of tadalafil relative to the larger, single doses tested in previous imaging studies.47

### CONCLUSIONS

- Tadalafil 5 mg once daily for 8 weeks in men with BPH-LUTS did not result in statistically significant changes compared with placebo detectable by RI or CPI measured by prostate ultrasonography.

- Although the study enrolled men with BPH-LUTS, the prostatic RI measured at baseline in this study was below the range reported in previous studies of men with BPH-LUTS2,47.

- The results for safety and tolerability were consistent with those observed in previous studies of tadalafil in men with BPH-LUTS.

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