**STUDY OBJECTIVES AND ENDPOINTS**

- The primary endpoint comparison was between tadalafil and placebo. Randomization was included as an active control.
- The primary endpoint was for on-demand or once daily treatment of ED, and
- Continuous efficacy measures. Changes in IPSS, TSS-BPH, and PGI-I were assessed following baseline (Visit 3) and the placebo lead-in period (Visit 2) in both groups, followed by 12 weeks of treatment with either tadalafil or tamsulosin in the same trial is of particular interest.

- A fixed-sequence testing procedure was used to control Type I error in analyses of primary and key secondary outcomes for tadalafil (but not tamsulosin), using the following pre-specified order: Total IPSS at endpoint, total IPSS at 4 weeks, BII at 4 weeks, and QoL at 4 weeks. A change had to be maintained across all four measures of providing adequate evidence of clinical meaningfulness at the 0.05 level. However, the results of all analyses and key secondary endpoints across all endpoints listed in the abstract, results provided were presented in the abstract.

**METHODS**

- The primary objective was to assess the efficacy of monotherapy with tadalafil 5 mg or tamsulosin 0.4 mg once-daily versus placebo on LUTS/BPH bother, quality of life, and only tadalafil improved ED.
- **RESULTS**
  - **Figure 2: Patien Disposition**
  - **Table 1: Baseline Characteristics of All Randomized Patients**

**SUMMARY**

- **CONCLUSIONS**
  - Both tadalafil and tamsulosin significantly improved LUTS/BPH as measured by IPSS as early as 1 week, and both improved QoL at endpoint. Only tadalafil significantly improved secondary LUTS/BPH measures of GSI, global improvement, and treatment satisfaction, and only tadalafil improved ED.

- **REFERENCES**