BACKGROUND

• Tadalafil, a long-acting phosphodiesterase type-5 inhibitor (PDE5i), was
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Efficacy and Safety of Tadalafil 5 mg Once Daily in Asian Males With Lower Urinary Tract Symptoms Secondary to Benign Prostatic Hyperplasia (BPH-LUTS): Integrated Analysis From 3 Asian Double-blind, Randomized, Placebo-controlled Clinical Studies

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RESULTS

Figure 1. Patient Disposition

Table 1. Individual Studies

Table 2. Baseline Demographics and Characteristics of Patients Treated With Tadalafil 5 mg Versus Placebo

Figure 4. CGI-I and CI-G (Endpoints) for Patients From the Analysis Group Who Completed These Assessments (n=458; Placebo; n=461; Tadalafil 5 mg)

Table 3. Changes From Baseline to Weeks 4, 8, and 12 in IPSS Parameters

Figure 2. Change From Baseline to Weeks 4, 8, and 12 in Total IPSS

Figure 3. Change From Baseline to Week 12 in IPSS Parameters

Table 4. Subgroup Analyses of Changes From Baseline to Week 12 (LOCF) in Total IPSS

Summary of Efficacy

Primary and secondary analyses

• In Asian men with BPH-LUTS, tadalafil 5 mg resulted in statistically significant improvements compared with placebo:

- Total IPSS compared with placebo (P=0.001) at 4, 8, and 12 weeks
- IPSS voiding and storage subscores and IPSS QoL score at Weeks 4, 8, and 12
- Differences in distribution of responses for both CGI-I and CI-GI significantly favored tadalafil 5 mg over placebo (P=0.001 for both)

Subgroup analyses

- IPSS total score demonstrated statistically significant improvements with tadalafil 5 mg once daily for 12 weeks (compared with placebo) regardless of baseline IPSS severity, previous alpha-blocker use, or prostate volume
- In the subgroup analysis for age, although the improvement of total IPSS in patients ≥65 years old was greater than that of patients <65 years old, the symptom severity of patients treated with tadalafil 5 mg at the end of the treatment measured by total IPSS was similar in both age categories

Table 5. Overall Safety Results

Summary of Safety

• In Asian men with BPH-LUTS, tadalafil 5 mg once daily for 12 weeks:

- Was generally safe and well tolerated
- Incidence of serious adverse events (SAEs) was low
- TEAEs (≥2% and more frequent) in patients receiving tadalafil compared with placebo include dyspepsia and headache

Limitations

- Based on our integrated analysis, it is difficult to extrapolate long-term efficacy and safety of tadalafil 5 mg once daily in Asian men with BPH-LUTS

CONCLUSIONS

• These integrated analyses revealed that tadalafil 5 mg once daily is efficacious in Asian males with BPH-LUTS across subgroups of BPH-LUTS severity, prior alpha-blocker use, and prostate volume

- No new safety concerns were identified in the integrated analyses

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References