

## **LONG- TERM SAFETY AND EFFICACY OF TADALAFIL 2.5--5MG DOSED ONCE DAILY IN MAN WITH ERECTILE DYSFUNCTION**

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**Introduced & Objectives:** With once daily (OD) administration of tadalafil, dosing and sexual activity would no longer need to be temporally linked for pts with ED. The aim was to evaluate long-term safety and efficacy of tadalafil 2.5 or 5mg dosed OD for the treatment of ED.

**Methods:** This study was conducted in the general ED population, 128 pts  $\geq 18$  Y of age were randomized in this double blind placebo-controlled trial and provided the supporting data for the approved OD dosing. In this trial, efficacy was measured using the International Index of Erectile Function (IIEF)-Erectile Function (-EF) domain scores, and Sexual Encounter Profile (SEP) measurement instruments. Safety measures included adverse events, electrocardiogram and clinical laboratory measures.

**Results:** In the 12-week mean IIEF-EF domain scores increased by 6.2 to an endpoint score of 19.4 and by 8.7 to 22.1 for 2.5 and 5 mg doses, respectively, versus an increase of 1.2 to 13.1 for placebo ( $p < 0.01$ ). Mean successful intercourse attempts (SEP 3) were 51% and 63% for tadalafil 2.5 and 5mg OD, respectively, versus 31% for placebo ( $p < 0.01$ ). The mean reported successful penetrations (SEP2) were 63% and 74%, respectively, compared with 45% in placebo ( $p < 0.01$ ). The profile of treatment – emergent AEs with tadalafil OD was similar to that previously reported with as needed treatments. AEs with tadalafil were reported in  $\leq 3\%$ .

**Conclusions:** Findings of this study support a favorable risk-benefit balance for tadalafil 2.5 or 5 mg, OD. Efficacy and safety findings were consistent with those with Tadalafil as needed.

The decision as to which treatment option is appropriate should be made based upon the pts goals.