



Study Reported Tadalafil Taken Once Daily Improved Erectile Function in Men with ED and Sexual Quality of Life in Couples

-- --Data Published in May Issue of Journal of Sexual Medicine

INDIANAPOLIS, May 6, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today announced results from a double-blind, placebo-controlled study which showed that tadalafil 5 mg dose taken once daily was generally well-tolerated, improved erectile function for men with erectile dysfunction (ED) and reported improvement in the sexual quality of life scores for men and their female partners. The 12-week study monitored 342 men and their partners, using several scientific questionnaires to assess changes in erectile function and sexual quality of life before and after treatment with a tadalafil once daily dose. The study appears in the May issue of the peer-reviewed Journal of Sexual Medicine.

"This is the first study of tadalafil 5 mg once daily dose in the treatment of men with ED in which the female partner reported improvement in sexual quality of life scores," said lead investigator Eusebio Rubio-Aurioles M.D., Ph.D. "The sexual quality of life scores also improved among males being treated. In addition, this study showed that daily dose of tadalafil is effective and generally well tolerated in the treatment of erectile dysfunction."

Study Findings

The 16-week double-blind, multicenter, randomized study followed 342 men with a minimum three-month history of ED, as well as their female partners who had adequate sexual function as measured by the Female Sexual Function Index (FSFI). Male candidates were excluded from the study if they: 1) had previously used tadalafil; 2) experienced ED as a result of other primary sexual disorders or related surgeries; 3) had a history of other medical conditions or treatments that could negatively impact erectile or cardiovascular function; or 4) had found other phosphodiesterase-5 (PDE5) inhibitor treatments to be ineffective in treating ED. The 26 investigation sites were located in Austria, France, Germany, Mexico and the United States.

In the first, four-week run-in phase of the study, men remained ED treatment-free and were asked to make a minimum of four sexual attempts with their partners. In the second, 12-week treatment phase of the study, men were randomized to receive either a placebo (N=78) or tadalafil 5 mg (N=264) taken once daily and were asked to make at least one sexual attempt with their partner per week.

Subjects were evaluated throughout the study using the International Index of Erectile Function (IIEF) Erectile Function (EF) Domain,(1) Sexual Encounter Profile (SEP) diary(2) and the Sexual Quality of Life (SQoL) domain of the Sexual Life Quality Questionnaire (SLQQ).(3) Each couple's responses were captured at entry, the end of each phase and following each sexual attempt. Changes in vital signs were also monitored to evaluate safety.

Results showed that tadalafil 5 mg taken daily significantly improved erectile function according to changes from baseline measured by the IIEF and SEP. The average increase from baseline to endpoint in the IIEF-EF domain was 7.9 points in the tadalafil group, compared with 0.7 points in the placebo group. Men in the tadalafil group reported a 28.6 percent increase on average (compared with 2.7 percent in the placebo group) in the ability to achieve an erection sufficient for vaginal penetration. When asked if their erections lasted long enough for successful intercourse, men in the tadalafil group reported a 46 percent increase on average in positive responses from baseline to endpoint, compared with 10.8 percent in the placebo group.

The study also reported a significant improvement in the sexual quality of life scores for men taking tadalafil once daily and their partners. The average increase in SQoL scores from baseline to endpoint for men in the tadalafil group was 39.5 points, compared with 12.5 point increase in the placebo group. The average increase in SQoL scores for women whose partners were in the tadalafil group was 32.4 points, compared with 5 points in the placebo group.

Tadalafil 5 mg was generally well-tolerated, and the most frequently reported adverse events were headache, dyspepsia and nasal congestion. Three subjects in the tadalafil group discontinued their participation in the study due to adverse events.

About Cialis

Cialis(R) (tadalafil) is approved for the treatment of erectile dysfunction on an as-needed basis or in a daily regimen. The recommended starting dose of Cialis for use as needed in most patients is 10 mg, taken prior to anticipated sexual activity. The dose may be increased to 20 mg or decreased to 5 mg, based on individual efficacy and tolerability. As part of a daily regimen,

Cialis may be taken as 2.5 mg or increased to 5 mg, based on individual efficacy and tolerability.

Important Safety Information for Cialis

Cialis is available by prescription only and is not for everyone. Men should discuss their medical conditions and all medications with their doctors to ensure Cialis is right for them and that they are healthy enough for sexual activity. Men taking nitrates, often used for chest pain, should not take Cialis. Such a combination could cause a sudden, unsafe drop in blood pressure. Cialis for once daily use provides continuous plasma tadalafil levels which should be considered when evaluating the potential for interactions with certain medications (e.g., nitrates, alpha-blockers, anti-hypertensives and potent inhibitors of CYP3A4) and with substantial amounts of alcohol.

Cialis does not protect a man or his partner from sexually transmitted diseases, including HIV. Men should not drink alcohol in excess with Cialis. The most common side effects with Cialis were headache, upset stomach, backache or muscle ache.

As with any ED tablet, in the rare event of priapism (an erection lasting more than four hours), men should seek immediate medical attention to avoid long-term injury.

In rare instances, men taking prescription ED tablets (including Cialis) reported a sudden decrease or loss of vision, or a sudden decrease or loss of hearing (sometimes with ringing in the ears and dizziness). It's not possible to determine if these events are related directly to the ED tablets or to other factors. If a man has a sudden decrease or loss of vision or hearing, he should stop taking any ED tablet including Cialis and seek medical attention right away.

For full patient information and/or full prescribing information, visit <http://www.cialis.com> or call 1-877-4-CIALIS

About Erectile Dysfunction (ED)

ED is defined as the consistent inability to attain and maintain an erection sufficient for sexual intercourse. As of 2004, it is estimated that approximately 189 million men worldwide will have ED.(4) Experts believe that 80 to 90 percent of ED cases are related to a physical or medical condition, such as diabetes, cardiovascular diseases, and prostate cancer treatment, while 10 to 20 percent are predominantly due to psychological causes.(5, 6) In many cases, however, both psychological and physical factors contribute to the condition.(7)

About Lilly

Lilly, a leading innovation-driven corporation is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

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- (1) The IIEF is a validated scale that assesses erectile function by measuring treatment-related responses in patients.
- (2) The SEP diaries contain five patient diary questions that allow patients to record responses following sexual events.
- (3) The SQoL domain contains 10 questions that compare the current sexual experience with the subject's experience prior to the onset of ED.
- (4) Data were extrapolated from Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ. Impotence and its Medical and Psychosocial Correlates: Results of the Massachusetts Male Aging Study, Journal of Urology. Vol. 151, 54-61, January 1994 and World Population Projection Program Of United Nations (2002 Revision) with indirect standardization.
- (5) Shabsigh, R. (2002). Back To Great Sex: Overcome ED and Reclaim Lost Intimacy. New York: Kensington.
- (6) Erectile Dysfunction, <http://kidney.niddk.nih.gov/kudiseases/pubs/impotence/>. Data accessed 09/28/07.
- (7) Lue, Tom F. Erectile Dysfunction. N Engl J Med 2000; 342: 1802-1813.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO>)

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