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New Data Show Cialis(R) (tadalafil) is Effective in Treating Erectile Dysfunction Caused by Traumatic Spinal Cord Injury

Patients Report Improved Erections and Erectile Function

BOTHELL, Wash. and INDIANAPOLIS, April 6, 2006 /PRNewswire-FirstCall via COMTEX News Network/ -- Data presented today at the 21st Congress of the European Association of Urology (EAU) show that when patients who had erectile dysfunction (ED) secondary to traumatic spinal cord injury (SCI) were treated with Cialis(R) (tadalafil)(1) (N=140), their International Index of Erectile Function (IIEF) Erectile Function (EF) Domain(2) scores improved from a mean baseline score of 13.5 to a score of 22.6 at endpoint. This is compared with placebo treated patients (N=44) with a mean baseline score of 13.0 and a score of 13.6 at endpoint. It is generally considered that an improvement of 4.0 points or more in the IIEF domain score reflects a clinically meaningful change.(3) Further, 54 percent of SCI patients treated with Cialis reported "normal" erectile function at the end of the treatment phase, as measured by the IIEF EF (IIEF EF domain score greater than or equal to 26).(4)

Study Analysis and Results

The efficacy of Cialis in patients with SCI was assessed by their scores on the IIEF EF domain, responses to the Sexual Encounter Profile (SEP)(5) diary question two (successful penetration) and question three (successful intercourse), and the Global Assessment Questionnaire(6) (GAQ) question one (improved erections). Tolerability was evaluated using treatment-emergent adverse events and vital signs collected at each assessment phase in the trial.

According to SEP diary question two(7), on average, patients receiving Cialis (N=139) reported the ability to penetrate their partner in 75.4 percent of attempts (43.6 percent at baseline). In patients receiving placebo (N=42), successful penetration was reported, on average, in 41.1 percent of attempts (44.9 percent at baseline). For SEP diary question three(8), on average, patients receiving Cialis (N=139) reported successful intercourse in 47.6 percent of attempts (10.8 percent at baseline). For patients receiving placebo (N=42), successful intercourse was reported, on average, in 16.8 percent of attempts (8.6 percent at baseline). For those patients receiving Cialis, the SEP diary questions two and three post-baseline scores were significantly different ($p < 0.001$) versus placebo.

According to GAQ question one (improved erections), 84.6 percent of patients (N=115) in the study reported improved erections after treatment with Cialis, whereas 19.5 percent of placebo treated patients (N=8) reported improved erections after treatment.

"Treating men for ED caused by a spinal cord injury is a complicated task. These results are encouraging for men who suffer from spinal cord injury," said Francois Giuliano, MD, PhD, Neuro-Urology Unit, Department of Physical Medicine and Rehabilitation, Raymond Poincare Hospital, Garches and Medical University of Paris West, France. "Tadalafil was not only effective in improving erections, it enabled more than half the men receiving tadalafil in the trial to achieve a normal erectile function score."

Study Design

In this study, 186 patients with a mean age of 38 were randomized to receive placebo or Cialis in a double-blind, parallel, flexible-dose study in four European countries (France, Germany, Italy and Spain). Patients were treated for 12 weeks with assessments after each four-week interval.

Following a four-week, treatment-free run-in period, patients were randomized to 10 mg Cialis or placebo. After this first treatment interval, patients receiving 10 mg Cialis were either increased to 20 mg Cialis or left unchanged based on patient response to the 10 mg Cialis dose. After the second treatment interval, Cialis dosing was increased, decreased, or unchanged, based on patient response to the first treatment interval.

The study population included patients with varying degrees of SCI severity. As determined by the American Spinal Injury Association (ASIA) scale, 69.4 percent (N=186) of patients had a complete spinal cord lesion, reflecting the greatest degree of neurological impairment. Further, patients with all levels of the spinal lesion (N=179, 84.3 percent thoracic or lumbo-sacral lesions) and all degrees of erectile dysfunction (N=184, 69 percent of patients had moderate to severe ED) were included.

Study results show that Cialis improved all efficacy endpoints when compared with placebo ($p < 0.001$). Cialis was generally well tolerated with mild or moderate treatment-emergent adverse events. The most common treatment-emergent adverse events (greater than or equal to 5 percent incidence) were headache (8.5 percent Cialis; 4.5 percent placebo) and urinary tract infection (7.7 percent Cialis; 6.8 percent placebo). Discontinuation due to an adverse event occurred in 2.8 percent of the patients receiving tadalafil and 2.3 percent of those receiving placebo.

About ED

ED is defined as the consistent inability to attain and maintain an erection sufficient for sexual intercourse. ED affects an estimated 189 million men worldwide.⁽⁹⁾ Experts believe that 80 - 90 percent of ED cases are related to a physical or medical condition, like diabetes, cardiovascular diseases, and prostate cancer treatment, while 10 - 20 percent are due to psychological causes.^(10,11) In many cases, however, both psychological and physical factors contribute to the condition.⁽¹²⁾

About Cialis

Cialis(R) (tadalafil) was approved by the FDA in November 2003 for the treatment of erectile dysfunction. Cialis is available by prescription only and is not for everyone. Men taking nitrates, often used for chest pain, should not take Cialis. Such a combination could cause a sudden, unsafe drop in blood pressure. The most common side effects with Cialis were headache, upset stomach, delayed 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. Men should not drink alcohol in excess with Cialis.

Cialis does not protect a man or his partner from sexually transmitted diseases, including HIV. In rare instances, men taking prescription ED tablets (including Cialis) reported a sudden decrease or loss of vision. 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, he should stop taking any ED tablet and seek immediate medical attention.

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. The standard recommended starting dose of Cialis for most patients is 10 mg. Patients with certain medical conditions or taking concomitant medications may need to start at a lower dose. For full patient information, visit <http://www.cialis.com>.

About Lilly ICOS LLC

Lilly ICOS LLC, a joint venture between ICOS Corporation (Nasdaq: ICOS) and Eli Lilly and Company (NYSE: LLY), developed tadalafil for the treatment of erectile dysfunction.

ICOS Corporation, a biotechnology company headquartered in Bothell, Washington, is dedicated to bringing innovative therapeutics to patients. ICOS is working to develop treatments for serious unmet medical conditions such as benign prostatic hyperplasia, hypertension, pulmonary arterial hypertension, cancer and inflammatory diseases. Additional information about ICOS is available at www.ICOS.com.

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. Additional information about Lilly is available at www.lilly.com.

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Except for historical information contained herein, this press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on current expectations, estimates and projections about the industry, management beliefs and certain assumptions made by the management of ICOS and Lilly. Investors are cautioned that matters subject to forward-looking statements involve risks and uncertainties, including economic, competitive, governmental, technological, legal and other factors discussed in the two companies' respective filings with the Securities and Exchange Commission, which may affect the business and prospects of the two companies and Lilly ICOS. Results and the timing and outcome of events may differ materially from those expressed or implied by the forward-looking statements in this press release. More specifically, there can be no assurance that Cialis will achieve commercial success or that competing products will not pre-empt market opportunities that might exist for the product.

(1) Cialis(R) is a registered trademark of Lilly ICOS LLC.

(2) The IIEF is a validated scale that assesses erectile function by measuring treatment-related responses in patients.

- (3) Mulhall J. Deciphering Erectile Dysfunction Drug Trials, Journal of Urology. Vol. 170, 353-358; August 2003.
- (4) Cappelleri JC, Rosen RC, Smith MD, Mishra A, Osterloh IH. Diagnostic evaluation of the erectile function domain of the International Index of Erectile Function. Urol, 1999;54; 346-351.
- (5) The SEP diaries contain five patient diary questions that allow patients to record responses following sexual events.
- (6) The Global Assessment Questionnaire, GAQ, is a self-administered questionnaire that allows patients to rate improvement in erectile function.
- (7) Were you able to insert your penis into your partner's vagina?
- (8) Did your erection last long enough for you to have successful intercourse?
- (9) 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.
- (10) Shabsigh, R. (2002). Back To Great Sex: Overcome ED and Reclaim Lost Intimacy. New York: Kensington.
- (11) Diseases and Conditions: Impotence,
<http://www.impotence.org/FAQ/index.asp>. Data accessed 11.20.03
- (12) Lue, Tom F. Erectile Dysfunction. N Engl J Med 2000; 342: 1802-1813.

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