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Clinical Data Shows Lilly ICOS' Cialis(R) (tadalafil) Improves Erectile Function in ED Patients with Significant, Multiple Comorbid Conditions

SAN ANTONIO, Texas, May 23, 2005 /PRNewswire-FirstCall via COMTEX/ -- Lilly ICOS LLC (NYSE: LLY and Nasdaq: ICOS) announced data today from an open-label clinical trial showing Cialis(R) (tadalafil)(1) improved erections in more than three-quarters of men who were suffering from erectile dysfunction (ED) and one or more comorbid conditions. These comorbidities include cardiovascular disease (including hypertension), diabetes, depression, hyperlipidemia, and prostate disease (including those who had undergone prostatectomy). On average, nearly 50 percent of all attempts resulted in an erection that lasted long enough to have successful sexual intercourse when patients were treated with Cialis 20 mg. This is compared to approximately 17 percent of attempts at baseline for this patient group. These data will be presented today at the 100th Annual Meeting of the American Urological Association (AUA).

"Treatment of ED in men with comorbid conditions is a challenge. It is exciting to see such positive results in this group of patients, who had a relatively high degree of severe ED and many of whom had multiple comorbidities," said Irwin Goldstein, M.D., Professor of Urology and Gynecology at the Boston University School of Medicine. "The findings confirm that Cialis improved erectile function in men with ED even when associated with significant comorbid conditions. Also, these patients tolerated treatment with Cialis very well."

Study Design & Key Findings

The MOMENTUS study (Multiple Observations in Men with ED in National Tadalafil Study in the United States) is a multi-center, open-label study that evaluated the efficacy and safety of Cialis 20 mg in 1,911 American men with ED who were enrolled into eight predefined groups. In this study, after a four-week treatment-free period to determine baseline ED, patients were instructed to take Cialis 20 mg as needed prior to sexual activity (not more than one dose a day) for a period of 12 weeks. The subgroup discussed here included 155 patients, mean age 65, who had significant comorbid conditions; many of these patients also had severe ED at baseline (51.9 percent). This subgroup comprised patients who met the enrollment criteria for the MOMENTUS trial but who could not be included in any other predefined group.

In the subgroup, 77.4 percent of patients reported an improvement in their erections after taking Cialis 20 mg based on the Global Assessment Questions (GAQ)(2), question one (Has the treatment you've been taking during this study improved your erections?). They also showed a 7.6 point improvement from the baseline score of 11.48 in the Erectile Function (EF) Domain Score of the International Index of Erectile Function (IIEF)(3). It is generally considered that an improvement of four points or more in the EF domain score reflects a clinically meaningful change(4).

After taking Cialis 20 mg, patients reported an increase from baseline in erections that resulted in "successful sexual intercourse" based on positive per patient response to Sexual Encounter Profile (SEP)(5) question three (Did your erection last long enough for you to have successful sexual intercourse?). On average, nearly half (49.4 percent) of the attempts resulted in an erection that lasted long enough for successful sexual intercourse, compared to the percentage at baseline of 16.9.

"Cialis provides a meaningful therapeutic benefit with regards to erectile function in men suffering from ED and significant comorbid conditions," said Sanjeev Ahuja, M.D., Associate Medical Director, Eli Lilly and Company. "Men who have ED should visit their doctor to discuss their sexual health and their overall health. This will give their doctor the opportunity to do a complete exam, during which significant health problems may be detected and addressed, and treatment options for ED can be discussed."

The most commonly reported side effects in the patients in this group were headache, flushing, nasal congestion, back pain, and upset stomach. Discontinuations due to adverse events in this group were three percent and similar to previously reported discontinuation rates in Cialis clinical trials. Not included in this clinical trial were patients with certain serious underlying cardiovascular conditions, including recent myocardial infarction, uncontrolled arrhythmias, hypotension (<90/50 mm Hg), uncontrolled hypertension (>170/100 mm Hg), unstable angina or angina occurring during sexual intercourse, or those who recently suffered a stroke or had severe heart failure.

Study Population

The table below depicts the baseline characteristics of age, severity of ED, and comorbid conditions among this subgroup of

patients.

Baseline Characteristics	Study group
AGE:	
Mean age (years)	65
ED SEVERITY:	
Severe ED (%)	51.9%
IIEF EF Domain Score	12.2
COMORBID CONDITIONS:	
Diabetes (%)	72.3%
Cardiovascular disease* (%)	
*60.6 percent of patients had hypertension	67.1%
Hyperlipidemia (%)	49.0%
Benign Prostatic Hyperplasia/Prostatectomy (%)	36.8%
Depression (%)	38.1%
MULTIPLE COMORBIDITIES:	
Have two or more comorbid conditions	84.5%

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(6). 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(7,8). In many cases, however, both psychological and physical factors contribute to the condition(9).

About Cialis

Cialis was approved by the FDA in November 2003 for the treatment of erectile dysfunction. Cialis is widely available throughout the world, including Australia, Brazil, Mexico, Canada, the United States and countries throughout Europe. More than 4.5 million patients worldwide have been treated with Cialis since its first introduction in February 2003.

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.

Men should discuss their medical conditions and medications, including alpha blockers for prostate problems or high blood pressure, with their doctors to ensure Cialis is right for them and that they are healthy enough for sexual activity. The most common side effects with Cialis were headache, upset stomach, delayed backache or muscle ache. Although rare, men who experience an erection for more than four hours (priapism) should seek immediate medical attention. Men should not drink alcohol in excess with Cialis. Cialis does not protect a man or his partner from sexually transmitted diseases, including HIV. 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.

Individual results may vary. Cialis studies were not designed to assess multiple intercourse attempts after a single dose. For full patient information, visit 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 marketing its product, Cialis (tadalafil), through Lilly ICOS LLC, for the treatment of erectile dysfunction. ICOS is working to develop treatments for serious unmet medical conditions such as benign prostatic hyperplasia, 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 GAQ is a self-administered questionnaire that allows patients to rate improvement in erections.

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

(4) Mulhall J. Deciphering Erectile Dysfunction Drug Trials, Journal of Urology. Vol. 170, 353-358; August 2003

(5) The SEP diaries contain five patient diary questions that allow patients to record responses following sexual events.

(6) 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.

(7) Shabsigh, R. (2002). Back To Great Sex: Overcome ED and Reclaim Lost Intimacy. New York: Kensington.

(8) Diseases and Conditions: Impotence,
<http://www.impotence.org/FAQ/index.asp>. Data accessed 11.20.03

(9) Lue, Tom F. Erectile Dysfunction. N Engl J Med 2000; 342: 1802-1813.

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