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New Analysis Shows Lilly ICOS' Cialis (tadalafil) is Effective

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An analysis of data from 11 clinical studies demonstrates that 82 percent of men suffering from erectile dysfunction (ED) and benign prostatic hyperplasia (BPH, or enlarged prostate), a common co-morbid condition, experienced improved erectile function when treated with Cialis® (tadalafil) 20 mg.¹ These data, as well as several other studies relating to Cialis, are to be presented this week at the 11th annual meeting of the International Society for Sexual and Impotence Research (ISSIR).

"It is often a discouraging experience to be diagnosed with BPH and to also have to deal with ED, which can be even more dispiriting," said Francesco Montorsi, M.D., from the Department of Urology, Universita Vita Salute San Raffaele, Milan, Italy. "These data show that men who have both BPH and ED and take Cialis experience improved erectile function."

Data from Men with ED and BPH

The data are from an analysis of 11 placebo-controlled, randomized ED clinical trials that included 2,102 men. The trials were designed to assess the efficacy and safety of Cialis for the treatment of ED, compared to placebo. Of the 2,102 men in these studies, 349 patients (17 percent) had also been diagnosed with BPH and randomized to use Cialis 10 mg or 20 mg, or placebo. After a 4-week treatment-free period to assess baseline level of erectile dysfunction, patients were treated with placebo or Cialis for 12 weeks. Among the BPH group, 105 patients were treated with placebo, 56 with Cialis 10 mg, and 188 with Cialis 20 mg.

Efficacy measures included the International Index of Erectile Function (IIEF, a scale that assesses the severity of ED and any improvement in erectile function based on responses to questions addressing the patient's experiences during sexual intercourse over the preceding four weeks), and a Global Assessment Questionnaire (GAQ) that a patient answers at the end of the treatment period regarding improvement in erections. Safety was evaluated in all patients by frequency and severity of treatment-emergent side effects.

Based upon responses to the GAQ, 82 percent of men with both ED and BPH reported improved erections when treated with Cialis 20 mg. Of men receiving Cialis 10 mg, 76 percent reported improved erections. In the placebo-treated group, 35 percent of men reported improved erections. Also, according to the analysis, nearly half (48 percent) of the men with BPH who took Cialis attained an erectile function domain score in the normal range of the IIEF at the end of treatment, compared to 11.3 percent on placebo. Cialis was well tolerated in this group of men. The most common side effects experienced by the patients on Cialis were headache, upset stomach and back pain.

About BPH

Benign Prostatic Hyperplasia (BPH) is a non-cancerous enlargement of the prostate that can occur in men with increasing age. When the prostate is enlarged, it may cause problems with urination. Symptoms include the urge for frequent urination, and a feeling that the bladder has not been emptied completely after urination. Treatment varies from medications to surgery and depends on how bothersome the symptoms are to the patient. Typical symptoms of BPH should be evaluated by a doctor to rule out any other health risks. BPH is common in older men. It is found in 60 percent of men over the age of 60.²

About 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 report having ED.³ 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.^{4,5} In many cases, however, both psychological and physical factors contribute to the condition.⁶

About Cialis

Cialis, approved by the FDA in November 2003 for the treatment of erectile dysfunction, is the only oral ED treatment shown to improve erectile function up to 36 hours in most men. Cialis can be taken without regard to food. The absorption of Cialis is not reduced by food, including high-fat foods. Cialis is currently available in approximately 100 countries, including Australia, Brazil, Mexico, Canada, the United States and countries throughout Europe. More than three 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, or certain alpha-blockers for prostate problems or high blood pressure, should not take Cialis. Such combinations could cause a sudden, unsafe drop in blood pressure.

Men should discuss their health status 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 should seek immediate medical attention. Men should not drink alcohol in excess with Cialis. Cialis studies were not designed to assess multiple intercourse attempts after a single dose. Cialis does not protect a man or his partner from sexually transmitted diseases, including HIV.

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.

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.

ICOS Corporation, a biotechnology company headquartered in Bothell, Washington, is dedicated to bringing innovative therapeutics to patients. ICOS is marketing its first 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 chronic obstructive pulmonary disease, cancer and inflammatory diseases.

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® is a registered trademark of Lilly ICOS LLC.

2. American Urological Association (AUA), *Benign Prostatic Hyperplasia (BPH): A Patients Guide*. Maryland: Education and Research Inc.

3. 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.

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

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

6. Lue, Tom F. Erectile Dysfunction. *N Engl J Med* 2000; 342: 1802-1813.