October 12, 2005

Lilly ICOS Announces Positive Results from Phase 2 Study of Tadalafil in Treating Symptoms of Benign Prostatic Hyperplasia

Study Involved Once-a-Day Dosing of Tadalafil; Company to Move Forward with Phase 3 Program

BOTHELL, Wash. & INDIANAPOLIS, Oct 12, 2005 (BUSINESS WIRE) -- Lilly ICOS LLC, a joint venture between Eli Lilly and Company (NYSE:LLY) and ICOS Corporation (Nasdaq:ICOS), announced positive results from a double-blind, placebo-controlled clinical study of tadalafil in the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia (BPH). The Phase 2 proof-of-concept study demonstrated clinically meaningful and statistically significant improvement in the primary endpoint, the International Prostate Symptom Score (IPSS), a seven-item questionnaire that assesses the severity of symptoms of BPH and the response to therapy. The IPSS is the standard scale used for the evaluation of medications that treat the symptoms of BPH. In addition, tadalafil demonstrated statistically significant improvement relative to placebo on most of the secondary endpoints included in the study.

Patients taking 5 mg tadalafil once-a-day, over a period of six weeks, experienced a mean 2.8 point improvement from baseline in the IPSS, compared to patients on placebo with a mean 1.2 point improvement. After stepping up to 20 mg tadalafil and continuing therapy once-a-day for another six weeks, patients experienced a mean 3.8 point improvement from baseline in the IPSS, compared to a mean 1.7 point improvement for patients on placebo. Both dosages showed clinically meaningful and statistically significant improvement in the primary endpoint. Additional results from the study of 250 patients will be presented at an upcoming medical congress.

In this Phase 2 study, the most frequently reported side effects were dyspepsia, back pain and headache. None of these side effects was reported by more than 5 percent of the study participants. There were no serious adverse events determined to be related to drug therapy. The reported adverse events were generally similar in this once-a-day study to those reported in other studies with tadalafil when administered on an as needed basis. The discontinuation rate due to adverse events was 3.6 percent for patients on tadalafil versus 1.4 percent on placebo. "We are delighted with the outcome of this study," said Paul Clark, ICOS Chairman, President and Chief Executive Officer. "BPH is a large market with room for new therapies that have a different mechanism of action. Investment in this indication makes a great deal of sense for Lilly ICOS, since many physicians treating patients for the current approved use of tadalafil also treat patients with BPH. We look forward to beginning the Phase 3 studies and confirming these results."

Claus Roehrborn, M.D., Professor and Chair of Urology, University of Texas, Southwestern Medical Center, Dallas, stated, "Millions of men over the age of 45 suffer from lower urinary tract symptoms and BPH. The prospect of having an additional treatment option for these bothersome urinary symptoms is most welcome news for those physicians engaged in caring for the aging male."

About BPH

Benign enlargement of the prostate gland or BPH can cause a number of troublesome urinary tract symptoms as a man ages. The enlarged prostate gland can irritate the bladder and it can also exert pressure upon the urethra, which is the passageway for urine leaving the bladder. The symptoms of BPH include difficulty initiating urination, straining to pass urine, frequent urination, repeated awakening at night to urinate, incomplete emptying of the bladder, and even the inability to urinate.

More than half of men over age 50 have symptoms caused by BPH. More than 50 percent of men with BPH also suffer from ED. (1) It has been estimated that 6 million men in the United States and Europe are prescribed medicines to relieve symptoms associated with BPH.(2) In 2004, total sales of medications to treat BPH in the United States and Europe were approximately $2.5 billion.(3)

About Tadalafil

Tadalafil is an inhibitor of the phosphodiesterase (PDE) type 5 and may cause relaxation of the smooth muscle within the prostate. Tadalafil, in response to sexual stimulation, also relaxes smooth muscle in blood vessels in penile tissue and is the active ingredient in Cialis® (tadalafil), a prescription drug which is approved for the treatment of erectile dysfunction (ED).

About Lilly ICOS LLC

Lilly ICOS LLC, a joint venture between ICOS Corporation (Nasdaq:ICOS) and Eli Lilly and Company (NYSE:LLY), is developing tadalafil.

ICOS Corporation, a biotechnology company headquartered in Bothell, Washington, is dedicated to bringing innovative therapeutics to patients. Through Lilly ICOS LLC, ICOS is marketing its first product, Cialis®. ICOS is working to develop treatments for serious unmet medical needs such as pulmonary arterial hypertension, benign prostatic hyperplasia, 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.

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 tadalafil will achieve commercial success or that competing products will not pre-empt market opportunities that might exist for the product.

The scientific information discussed in this news release related to our product candidate is preliminary and investigative. Such product candidate is not approved by the U.S. Food and Drug Administration (FDA) for this use, and no conclusions can or should be drawn regarding the safety or effectiveness of the product for the indication being investigated. In the United States, only the FDA can determine whether the product candidate is safe and effective for the use(s) being investigated.

(1) Hoesl CE, et al., European Urology, Vol. 47(4), April 2005.
(2) Benign Prostatic Hyperplasia, Decision Resources, April 2001.
(3) Data on file.
SOURCE: ICOS Corporation
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