

# FDA Approves Cialis® (tadalafil) for Once Daily Use for the Treatment of Erectile Dysfunction

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## **-Approval Makes Available New Daily Dosing Option for the Treatment of ED-**

INDIANAPOLIS, Jan 08, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) announced today that the U.S. Food and Drug Administration (FDA) has approved Cialis® (tadalafil)(1) for once daily use (2.5 mg and 5 mg), an oral medication taken once per day to treat erectile dysfunction (ED). When Cialis for once daily use is taken daily, men can attempt sexual activity at anytime between doses.

Currently available in parts of Europe, this low-dose daily treatment option of Cialis may be most appropriate for men with ED who anticipate more frequent sexual activity (e.g. twice weekly). For other men, Cialis taken as needed - the previously approved dosing regimen - may be most appropriate.

In clinical trials, when taken without restrictions on the timing of sexual activity, Cialis for once daily use improved erectile function over the course of therapy.

"ED can be a chronic condition like diabetes or high blood pressure," said Ridwan Shabsigh, M.D., Director of the Division of Urology at Maimonides Medical Center in New York. "As a urologist, I know couples like to have choices and will appreciate the availability of Cialis for once daily use."

Cialis for use as needed transformed the U.S. ED market when it was approved in 2003 as the first and only PDE5 inhibitor clinically proven to provide sustained efficacy for up to 36 hours. Cialis for once daily use provides a new option for men who may be looking for a dosing option that can be taken without regard to timing of sexual activity. In consultation with their physician, patients now have the freedom to choose the dosing regimen that is appropriate for them.

"We strive to provide patients with solutions that fit their needs and Cialis for once daily use delivers on this promise," said Shawn Heffern, Cialis U.S. Director of Brand Marketing at Lilly. "Now, patients have two options - some may prefer the up to 36 hours of efficacy provided by Cialis for use as needed while others may want the unique benefit provided by this daily dosing option."

Additionally, Lilly's wholesale pricing for Cialis for once daily use will be comparable to Cialis for use as needed such that patients who currently use two or more pills per week of Cialis for use as needed should not experience higher treatment costs with Cialis for once daily use.

The FDA's approval of Cialis for once daily use was based upon the evaluation of the comprehensive data package for the daily dosing option. The data include results from three phase III randomized, double-blind, placebo- controlled studies. Men with ED who participated in these clinical studies and who took tadalafil 2.5 mg and 5 mg once daily without regard to their timing of sexual activity experienced improved erectile function compared with those taking placebo.(2) Cialis 5 mg, 10 mg and 20

mg have been approved in the United States for as-needed treatment of ED since November 2003.

The most commonly reported adverse events were headache, indigestion, back pain, muscle aches, nasal congestion, flushing and pain in limb. Most adverse events reported with tadalafil were transient and generally mild or moderate.

#### About ED

ED is defined as the consistent inability to attain and maintain an erection sufficient for sexual intercourse. Experts believe that 80 percent 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 percent to 20 percent are predominantly due to psychological causes.(3,4) In many cases, however, both psychological and physical factors contribute to the condition.(5)

#### About Cialis

Cialis® (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. 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.

In rare instances, men taking prescription ED tablets (including Cialis) reported a sudden decrease or loss of vision or 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 and seek medical attention right away.

Cialis does not protect a man or his partner from sexually transmitted diseases, including HIV. Men should not drink alcohol in excess with Cialis. Individual results may vary. Cialis has not been studied for multiple attempts per dose.

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### About Eli Lilly and Company

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 world-wide 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](http://www.lilly.com). P-LLY

Certain of the matters discussed herein with respect to clinical studies and Lilly's products may constitute 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 management. Investors are cautioned that matters subject to forward- looking statements involve risks and uncertainties, including economic, competitive, governmental, technological and other factors discussed in the respective filings with the Securities and Exchange Commission, which may affect the business and prospects of Lilly. More specifically, there can be no assurance that this product will achieve commercial success or that competing products will not pre-empt any market opportunity that might exist for the product.

- (1) Cialis is a registered trademark of Eli Lilly.
- (2) Cialis prescribing information, updated January 2008.
- (3) Shabsigh, R. (2002). Back To Great Sex: Overcome ED and Reclaim Lost Intimacy. New York: Kensington.
- (4) Erectile Dysfunction, <http://kidney.niddk.nih.gov/kudiseases/pubs/impotence/>. Data accessed 09/28/07.
- (5) Lue, Tom F. Erectile Dysfunction. N Engl J Med 2000; 342: 1802-1813.

SOURCE Eli Lilly and Company