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New Study Shows Men Taking Cialis® (tadalafil) Tablets Once Daily Returned to Normal Erectile Function after Incomplete Response to As-Needed PDE5 Inhibitor Therapy

Data published in the Journal of Sexual Medicine

INDIANAPOLIS, July 16, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that study results published in the Journal of Sexual Medicine showed a greater percentage of men who had an incomplete response to as-needed PDE5 inhibitor treatment returned to normal erectile function when given Cialis once daily, compared to placebo, as measured by the erectile function domain of the International Index of Erectile Function (IIEF-EF). In a pre-specified secondary measure, Cialis significantly improved erectile function scores versus placebo in those men who had an incomplete response to as-needed PDE5 treatment.

Cialis is a phosphodiesterase type 5 inhibitor approved by the Food and Drug Administration (FDA) for erectile dysfunction (ED), the signs and symptoms of benign prostatic hyperplasia (BPH) and both ED and the signs and symptoms of BPH (ED+BPH).

"PDE5 inhibitors are highly effective for most men when taken as-needed, but responses can range from minimal change to a return to normal erectile function," said Dr. Edward D. Kim, MD, of the Division of Urology, Department of Surgery, University of Tennessee Graduate School of Medicine and lead author of the study. "We believe the study outcome will help prescribers make better informed decisions when treating their patients."

It is important to note that Cialis is not to be taken with medicines called "nitrates" such as isosorbide dinitrate or isosorbide mononitrate which are often prescribed for chest pain; or with recreational drugs called "poppers" like amyl or butyl nitrite, as the combination may cause an unsafe drop in blood pressure; or if allergic to Cialis or Adcirca® (tadalafil), or any of its ingredients. Anyone who experiences any symptoms of an allergic reaction, such as rash, hives, swelling of the lips, tongue or throat, or difficulty breathing or swallowing, should call a healthcare provider or get help right away.

About the Study

The randomized, double-blind, parallel, placebo-controlled trial was conducted in 51 sites in the United States and Canada. The study enrolled men with ED aged 18 years and older who had some response (IIEF-EF \geq 17) but were unable to reach normal erectile function (IIEF-EF $<$ 26) while on a maximum dose of an as-needed PDE5 inhibitor treatment. The study assessed whether Cialis for once daily use is superior to placebo in returning these men to normal erectile function. A total of 623 subjects were randomly assigned to receive treatment with Cialis for once daily use or placebo.

The primary objective was to determine whether a significantly greater percentage of incomplete responders had a return to normal erectile function when treated with tadalafil 2.5 titrated to 5 mg and 5 mg once daily compared to placebo. The key secondary objective was evaluation of the efficacy of tadalafil 2.5 titrated to 5 mg and 5 mg once daily compared to placebo, as measured by change from baseline to endpoint in IIEF-EF.

The International Index of Erectile Function-Erectile Function Domain (IIEF-EF) is a questionnaire evaluating sexual function where higher scores indicate better erectile function.

Treatment with Cialis 2.5 mg to 5 mg and 5 mg met the primary endpoint, resulting in significantly higher percentages of men (38.7 percent and 39.6 percent, respectively) with IIEF-EF domain scores in the normal range (\geq 26) through 12 weeks versus placebo (12.1 percent; both, $p < .001$). At week 4, significantly greater percentages of men being treated with Cialis 2.5 to 5 mg and 5 mg (33.5 percent and 41.1 percent, respectively) had experienced a return to normal erectile function (placebo, 8.5 percent; both, $p < .001$).

For the key secondary objective, improvements in the IIEF-EF domain score were statistically significant for the tadalafil 2.5- to 5-mg group (8.1) and the tadalafil 5-mg group (8.0), compared to the placebo group (1.9; both, $p < .001$).

The most common treatment-emergent adverse events observed in the study were consistent with other Cialis studies and included headache, back pain and upset stomach. Three Cialis 2.5 mg to 5 mg subjects, three Cialis 5 mg subjects and two placebo subjects discontinued study participation due to an adverse event (AE). Nasal congestion was the only AE leading to

discontinuation reported by more than one subject (two subjects in the tadalafil 2.5 to 5 mg group).

About Cialis

Cialis is indicated for the treatment of men with erectile dysfunction (ED), men with the signs and symptoms of benign prostatic hyperplasia (BPH), and men with both ED and the signs and symptoms of BPH.

Cialis is not for women or children.

Important Safety Information for Cialis® (tadalafil) tablets

What Is The Most Important Information I Should Know About Cialis?

Do not take Cialis if you:

- **take medicines called "nitrates"** such as isosorbide dinitrate or isosorbide mononitrate which are often prescribed for chest pain as the combination may cause an unsafe drop in blood pressure
- use recreational drugs called "poppers" like amyl nitrite and butyl nitrite
- **are allergic to Cialis or Adcirca® (tadalafil), or any of its ingredients.** Call your healthcare provider or get help right away if you experience any symptoms of an allergic reaction, such as **rash, hives**, swelling of the lips, tongue or throat, or difficulty breathing or swallowing

After taking a single tablet, some of the active ingredient of Cialis remains in your body for more than 2 days. The active ingredient can remain longer if you have problems with your kidneys or liver, or you are taking certain other medications.

Stop sexual activity and get medical help right away if you get symptoms such as chest pain, dizziness, or nausea during sex. Sexual activity can put an extra strain on your heart, especially if your heart is already weak from a heart attack or heart disease.

What Should I Tell My Healthcare Provider Before Taking Cialis?

Cialis is not right for everyone. Only your healthcare provider and you can decide if Cialis is right for you. Ask your healthcare provider if your heart is healthy enough for you to have sexual activity. You should not take Cialis if your healthcare provider has told you not to have sexual activity because of your health problems. Before taking Cialis, tell your healthcare provider about all your medical problems, particularly if you have or ever had:

- **heart problems** such as chest pain (angina), heart failure, irregular heartbeats, or have had a heart attack
- **high or low blood pressure** or have high blood pressure that is not controlled
- **stroke**
- **liver or kidney problems or require dialysis**
- **retinitis pigmentosa**, a rare genetic (runs in families) eye disease
- **severe vision loss, including a condition called NAION**
- **stomach ulcers or a bleeding problem**
- **a deformed penis shape** or Peyronie's disease
- **an erection that lasted more than 4 hours**
- **blood cell problems** such as sickle cell anemia, multiple myeloma, or leukemia

Can Other Medicines Affect Cialis?

Tell your healthcare provider about all the medicines you take especially if you take:

- medicines called "nitrates" which are often prescribed for chest pain
- alpha-blockers often prescribed for prostate problems
- blood pressure medications
- medicines for HIV or some types of oral antifungal medications
- some types of antibiotics such as clarithromycin, telithromycin, erythromycin (several brand names exist, please contact your healthcare provider to determine if you are taking this medicine)
- other medicines or treatments for erectile dysfunction (ED)
- Cialis is also marketed as Adcirca for the treatment of pulmonary arterial hypertension. Do not take both Cialis and Adcirca. Do not take sildenafil citrate (Revatio®)* with Cialis.

What Should I Avoid While Taking Cialis?

- Do not use other ED medicines or ED treatments while taking Cialis.
- Do not drink too much alcohol when taking Cialis (for example, 5 glasses of wine or 5 shots of whiskey). Drinking too much alcohol can increase your chances of getting a headache or getting dizzy, increasing your heart rate, or lowering your blood pressure.

What Are The Possible Side Effects Of Cialis?

The most common side effects with Cialis are: headache, indigestion, back pain, muscle aches, flushing, and stuffy or runny nose. These side effects usually go away after a few hours. Men who get back pain and muscle aches usually get it 12 to 24 hours after taking Cialis. Back pain and muscle aches usually go away within 2 days. Call your healthcare provider if you get any side effect that bothers you or one that does not go away.

Uncommon but serious side effects include:

An erection that won't go away: If you get an erection lasting more than 4 hours, seek immediate medical help 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 you have a sudden decrease or loss of vision or hearing, stop taking any ED tablet, including Cialis and call a healthcare provider right away.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Cialis does not:

- cure ED
- increase a man's sexual desire
- protect a man or his partner from sexually transmitted diseases, including HIV
- serve as a male form of birth control

Cialis is available by prescription only. For additional information, talk to your doctor and see full Patient Information at <http://pi.lilly.com/us/cialis-ppi.pdf> and Prescribing Information at <http://pi.lilly.com/us/cialis-pi.pdf>, or visit www.cialis.com for more information.

* The brand listed is a trademark of its respective owner and is not a trademark of Eli Lilly and Company. The maker of this brand is not affiliated with and does not endorse Eli Lilly and Company or its products.

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About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of 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.

This press release contains forward-looking statements about the use of Cialis for the treatment of erectile dysfunction reflects Lilly's current beliefs. However, as with any pharmaceutical product under development, there are substantial risks and uncertainties in the process of development, commercialization, and regulatory review. There is no guarantee that the product will receive additional regulatory approvals. There is also no guarantee that the product will continue to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

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