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Cialis® (tadalafil) Tablets Recommended for Approval for the Treatment of the Signs and Symptoms of Benign Prostatic Hyperplasia in the European Union

Milestone reflects Eli Lilly and Company's commitment to bring new treatment options to millions of men who experience urological conditions

INDIANAPOLIS, Sept. 21, 2012 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in the European Union (EU), recommending approval of Cialis 5 mg for once daily use for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH).

The opinion is now referred for final action to the European Commission, which has the authority to approve medicines for the EU. The Commission usually decides on CHMP recommendations within one to two months.

Cialis was approved for erectile dysfunction (ED) in the EU in 2002. Cialis for once daily use was approved for the treatment of ED in the EU in 2007.

"If approved by the European Commission, Cialis will be the only medication in the EU to provide a single treatment option for men with both ED and BPH," said Anthony Beardsworth, senior medical director at Lilly. "The CHMP positive opinion for Cialis marks an important regulatory milestone for Eli Lilly and Company and our commitment to bringing new treatment options to the millions of men who experience ED and BPH."

Cialis 5 mg for once daily use was approved by the U.S. Food and Drug Administration (FDA) in October 2011 for the treatment of the signs and symptoms of BPH. The FDA also approved Cialis 5 mg for once daily use to treat men who have both erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (ED+BPH).

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. It also should not be taken by those who are 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 their healthcare provider or get help right away.

In addition to the U.S., Cialis for once daily use has been approved to treat the signs and symptoms of BPH in Canada, Mexico, Brazil, South Korea, Russia, Panama, Argentina, Honduras, Ecuador, Costa Rica, Colombia and Israel.

About ED and BPH

ED is a condition where the penis does not fill with enough blood to harden and expand when a man is sexually excited, or when he cannot keep an erection. Approximately 50 percent of men between 40-70 years old have ED.^[1]

BPH is a condition where the prostate enlarges, which can cause urinary symptoms.

ED and BPH are conditions that may occur in the same patient. Several studies have shown that many men with ED also experience the symptoms of BPH.^{[2],[3],[4]}

About Cialis

Cialis is currently approved for ED in more than 100 countries throughout the world.

In the United States, Cialis provides men with ED two different dosing options — Cialis for once daily use (2.5 mg and 5 mg) and Cialis for use as needed (5 mg, 10 mg and 20 mg). Cialis is not to be taken more than one time each day.

Cialis for once daily use is approved to treat ED, the signs and symptoms of BPH, and ED and the signs and symptoms of BPH in men who have both conditions (ED+BPH). Cialis 5 mg for once daily use is the recommended dose to treat BPH and ED+BPH.

Cialis for once daily use can help men with ED be ready anytime between doses^{*}, so they do not have to plan sexual activity around taking a pill. It can also treat the signs and symptoms of BPH. Cialis for once daily use is the only medication approved to treat both ED and the signs and symptoms of BPH.

Cialis for use as needed is approved to treat erectile dysfunction (ED). Cialis for use as needed should be taken before sexual activity. It may go to work quickly (in as little as 30 minutes in some men) and can work up to 36 hours.^{*+}

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 two days.

^{*} Individual results may vary. Not studied for multiple attempts per dose.

⁺In clinical trials, Cialis for use as needed started to work in 30 minutes for some men who took 20 mg of Cialis for use as needed. When taken as needed, Cialis was shown to improve, up to 36 hours after dosing, the ability of men with ED to have a single successful intercourse attempt.

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.

This press release contains forward-looking statements about the potential of Cialis for the treatment of benign prostatic hyperplasia and 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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[1] Feldman HA et al. Impotence and its medical and psychosocial correlates: results of the Massachusetts Male Aging Study. J Urol. 1994;151(1):54-61.

[2] Rosen R, Altwein J, Boyle P, Rogler SK, Lukacs B, Meuleman E, et al. Lower urinary tract symptoms and male sexual dysfunction: the multinational survey of the aging male (MSAM-7). Eur Urol. 2003;44(6):637-649.

[3] Brookes ST, Link CL, Donovan JL, and McKinlay JB. Relationship between lower urinary tract symptoms and erectile dysfunction: results from the Boston Area community Health Survey. J Urol 2008;179:250-255.

[4] Gacci M, et al. Critical analysis of the relationship between sexual dysfunctions and lower urinary tract symptoms due to benign prostatic hyperplasia. Eur Urol 2011; 60:809-825.

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