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New Study of Cialis® (tadalafil) Tablets Co-administered with Finasteride Meets Primary Endpoint in Men with Lower Urinary Tract Symptoms of Benign Prostatic Hyperplasia

Phase 3 data presented at European Association of Urology Congress

INDIANAPOLIS, March 18, 2013 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) presented results today at the annual European Association of Urology (EAU) Congress in Milan, Italy, of a study that showed Cialis 5 mg once daily co-administered with finasteride significantly improved scores on the International Prostate Symptom Score (IPSS), compared to placebo/finasteride, in men with lower urinary tract symptoms of benign prostatic hyperplasia (LUTS/BPH) and enlarged prostates. On a pre-specified secondary measure, Cialis/finasteride also improved erectile function scores versus placebo/finasteride in those men who had both LUTS/BPH and erectile dysfunction (ED) at baseline.

This is the first study to report co-administration of Cialis and finasteride in men with LUTS/BPH. Cialis is a phosphodiesterase type 5 inhibitor approved by the Food and Drug Administration (FDA) for the signs and symptoms of BPH and both ED and the signs and symptoms of BPH (ED+BPH). Finasteride is a type II 5alpha-reductase inhibitor (5-ARI) approved by the FDA for the treatment of BPH in men with an enlarged prostate.

"Symptomatic improvement with 5-ARI therapy (finasteride) is observed after six to twelve months of treatment; therefore, the study aimed to understand if men with prostatic enlargement experience earlier improvement of BPH symptoms when tadalafil is co-administered with a 5-ARI therapy," said Claus Roehrborn, MD, chairman, Department of Urology, The University of Texas Southwestern Medical Center, who presented the results during the EAU Congress. "These results can help prescribers make better informed decisions when treating their patients."

About the Study

The randomized, double-blind, placebo-controlled, 26-week trial assessed the efficacy and safety of Cialis 5 mg for once daily use or placebo co-administered with finasteride in 696 men aged 45 years and older with an International Prostate Symptom Score (IPSS) of at least 13, a urine flow rate (Qmax) of 4 millimeters per second (mL/sec) to 15 mL/sec and a prostate volume at least 30 mL.

The primary measure was the International Prostate Symptom Score (IPSS), a questionnaire evaluating lower urinary tract symptoms (LUTS) occurring during the preceding month where lower scores indicate less severe LUTS. Pre-specified secondary measures included the International Index of Erectile Function-Erectile Function Domain (IIEF-EF), a questionnaire evaluating sexual function where higher scores indicate better erectile function, and the Treatment Satisfaction Scale-Benign Prostatic Hyperplasia (TSS-BPH), a validated, disease-specific 13-item questionnaire used to assess patients' perceptions of satisfaction with efficacy, dosing and side effects, with lower scores indicating greater satisfaction with treatment.

Cialis/finasteride met the primary endpoint, significantly improving IPSS total scores through 12 weeks versus placebo/finasteride (-5.2 versus -3.8, $p = 0.001$). Cialis/finasteride also significantly improved IPSS total scores versus placebo/finasteride at 4 weeks (-3.9 versus -2.3, $p < 0.001$) and 26 weeks (-5.5 versus -4.5, $p = 0.022$).

On the key secondary measure, Cialis/finasteride improved IIEF-EF scores in sexually active men with ED versus placebo/finasteride at Week 4 (2.7 versus -1.4, $p < 0.001$), Week 12 (4.2 versus 0.5, $p < 0.001$) and Week 26 (3.9 versus -0.3, $p < 0.001$).

The TSS-BPH improved with Cialis/finasteride versus placebo/finasteride at 26 weeks (2.0 versus 2.1, $p = 0.031$), driven by satisfaction with efficacy ($p = 0.025$), with no significant difference for dosing or side effects.

The most common treatment-emergent adverse events (TEAEs) were headache (Cialis/finasteride 12 [3%]; placebo/finasteride 12 [3 %]), indigestion (Cialis/finasteride 8 [2%]; placebo/finasteride 2 [.5 %]) and back pain (Cialis/finasteride 1 [.3%]; placebo/finasteride 0 [0 %]).

About BPH and ED

Benign prostatic hyperplasia (BPH) is a condition where the prostate enlarges, which can cause urinary symptoms like needing to go urgently and frequently.

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.

BPH and ED are conditions that may occur in the same patient. Several studies have shown that many men with ED also experience the symptoms of BPH.^{[1],[2],[3]}

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.

This press release contains forward-looking statements about the use of Cialis for the treatment of benign prostatic hyperplasia and 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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[1] Rosen R, Altwein J, Boyle P, Roger 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.

[2] 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.

[3] Gacci M, et al. Critical analysis of the relationship between sexual dysfunctions and lower urinary tract symptoms due to benign prostatic hyperplasia. In press. Eur Urol 2011; doi:10.1016/j.eururo.2011.06.037.

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