



May 28, 2014

## **Sanofi and Lilly announce licensing agreement for Cialis® (tadalafil) OTC**

### **Companies anticipate providing over-the-counter (OTC) product to treat erectile dysfunction after expiration of certain patents**

PARIS and INDIANAPOLIS, May 28, 2014 /PRNewswire/ -- Sanofi (EURONEXT: SAN and NYSE: SNY) and Eli Lilly and Company (NYSE: LLY) today announced an agreement to pursue regulatory approval of nonprescription Cialis (tadalafil). Cialis is currently available by prescription only worldwide for the treatment of men with erectile dysfunction (ED).

Under the terms of the agreement, Sanofi acquires the exclusive rights to apply for approval of Cialis OTC in the United States, Europe, Canada and Australia. Sanofi also holds exclusive rights to market Cialis OTC following Sanofi's receipt of all necessary regulatory approvals. If approved, Sanofi anticipates providing Cialis OTC after expiration of certain patents. Terms of the licensing agreement were not disclosed.

"This agreement provides us with an opportunity to work with Lilly, a leader in men's health, to transform how this important medicine is offered to millions of men throughout the world," said Vincent Warnery, senior vice president, Global Consumer Healthcare Division, Sanofi. "The opportunity to forge an industry-leading partnership that adds to Sanofi Consumer Healthcare's leading portfolio and successful track record of over-the-counter switches reinforces consumer health care as a major growth platform for Sanofi."

"Millions of men worldwide trust Cialis to treat ED. We are pleased to work with Sanofi to pursue a path that could allow more men who suffer from ED to obtain convenient access to a safe and reliable product without a prescription," said David Ricks, senior vice president, Lilly, and president, Lilly Bio-Medicines. "Switching a medicine to over-the-counter is a highly regulated process that is data-driven and scientifically rigorous. Together with Sanofi, we look forward to working closely with regulatory authorities to define the proper actions and necessary precautions to help patients use over-the-counter Cialis appropriately."

Cialis was first approved by the European Medicines Agency in 2002, then by the U.S. Food and Drug Administration in 2003, for the treatment of erectile dysfunction. Ultimately, Cialis has received approval in more than 120 countries for indications that vary by country, including erectile dysfunction and the signs and symptoms of benign prostatic hyperplasia (BPH). Cialis reached \$2.16 billion USD (€1.58 billion) in worldwide sales in 2013 and has recorded total global sales of more than \$14 billion USD (€10.2 billion) since launch. To date, more than 45 million men worldwide have been treated with Cialis.

#### **About Cialis**

Currently only available with a prescription, Cialis is a tablet taken to treat erectile dysfunction (ED), the signs and symptoms of benign prostatic hyperplasia (BPH), and both ED and the signs and symptoms of BPH. Cialis is the only PDE-5 inhibitor treatment that offers men a choice when it comes to treatment for erectile dysfunction - Cialis for use as needed and Cialis for once daily use. To learn more about Cialis, visit [www.cialis.com](http://www.cialis.com).

Cialis is not for women or children. 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 Erectile Dysfunction (ED)**

ED is a medical condition in which a man has trouble getting or keeping an erection. It is very common: more than half of men over 40 years old have ED.[i]

#### **About Sanofi Consumer Healthcare**

Sanofi Consumer Healthcare is committed to providing consumers around the world with self-care solutions that empower them

to better manage their health and well-being through leading brands in the areas of Allergy, Digestive health, Feminine care, Cough, cold, flu & sinus and Vitamins, minerals & supplements. We place people at the very heart of everything we do and strive to identify and fulfil their needs by delivering consumer insights-driven innovation, leveraging our medical & scientific heritage and our close collaboration with healthcare professionals, easing consumer access via switching relevant prescription medicines to over-the-counter solutions and applying the pharmaceutical quality standards delivered by our Group's global manufacturing network. In 2013, Sanofi Consumer healthcare achieved a €3.0 billion (\$4.1 billion USD) turnover representing a 5.2% growth vs. 2012 (constant exchange rates) and ranked #3 worldwide consumer healthcare player (Nicholas Hall- 2013).

## About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY). To learn more about Sanofi, please visit us at [www.sanofi.com](http://www.sanofi.com).

## About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and <http://newsroom.lilly.com/social-channels>.

## Indications

Cialis is available via prescription only and is approved to treat erectile dysfunction, or ED (2.5 mg, 5 mg, 10 mg, 20 mg), and both ED and the signs and symptoms of benign prostatic hyperplasia, or BPH (5 mg). Taking Cialis with finasteride when starting BPH treatment has been studied for 26 weeks. Cialis is not for women or children.

## Important Safety Information for CIALIS<sup>®</sup> (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<sup>®</sup> (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](http://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 healthcare provider and please see the [Full Prescribing Information](#), and [Medication Guide](#). You may also learn more about Cialis at [www.cialis.com](http://www.cialis.com).**

\* 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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[i] Feldman HA, Goldstein I, Hatzichristou DG, Krane RJ, McKinlay JB. Impotence and its medical and psychosocial correlates: results of the Massachusetts Male Aging Study. J Urol. 1994;151:54-61.

## Forward Looking Statements

*This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as*

amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's and Lilly's management believe that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of the companies, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. In particular, there are no guarantees that regulatory authorities will approve Cialis for nonprescription use. Risks and uncertainties also include, among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Companies' ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2013, and in the public filings with the SEC made by Lilly, including those listed under "risk Factors" in Lilly's annual report on Form 10-K for the year ended December 31, 2013. Other than as required by applicable law, the companies do not undertake any obligation to update or revise any forward-looking information or statements.

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The Lilly logo is rendered in a vibrant red, cursive script font. The letters are fluid and interconnected, with a prominent 'L' at the beginning and a long, sweeping tail on the 'y' that extends downwards and to the right. The overall appearance is elegant and professional, characteristic of the pharmaceutical company's branding.



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Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

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