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Lilly ICOS' Cialis (tadalafil) Makes Impressive Strides in First Six Months on the U.S. ED Treatment Market

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Cialis Leads Market in New Treatment Initiations and Switches for April

After only six months, Cialis[®] (tadalafil)¹, the latest oral erectile dysfunction (ED) treatment on the market in the U.S., is challenging Viagra[®] (sildenafil citrate)² for share of the ED market as Cialis leads in new treatment initiations by urologists³ and switches from other products for April. Cialis is marketed by Lilly ICOS LLC, a joint venture between Eli Lilly and Company (NYSE: LLY) and ICOS Corporation (Nasdaq: ICOS). Cialis is the only ED treatment shown to improve erectile function up to 36 hours in most men. Cialis can be taken without regard to food.

Cialis Leads in New Treatment Initiations

- According to market research firm ImpactRx[™] (which tracks the habits of a panel of high prescribing physicians and may reflect emerging trends in doctors' offices today)⁴, U.S. urologists initiated treatment with Cialis in April at a rate of more than two-to-one over each of the other oral ED treatments. In fact, Cialis represented 56 percent of new treatment initiations by urologists in April, compared to 21 percent for Levitra (vardenafil HCl)⁵ and 23 percent for Viagra.⁶
- Based on data from IMS, another source of market information, in April, Cialis represented 30 percent of new ED treatment prescriptions written by urologists, compared to 16 percent for Levitra and 54 percent for Viagra.⁷

Cialis Leads in Switches

- In April, nearly two thirds of all men who switched their oral ED treatment switched to Cialis. Following is information from ImpactRx[™] on share of new prescriptions written in April by doctors changing their patients' ED treatment from product to another.

	Primary Care Physicians	Urologists
Cialis	60%	69%
Levitra	36%	26%
Viagra	4%	5%

In an independent clinical study, more men selected Cialis as their preferred treatment of choice after trying different oral ED medications, primarily because of how long the drug worked.⁸ This may explain why many men with ED who are on oral treatment are switching to Cialis.

Cialis Challenges Viagra

The percentages of new prescriptions written by all doctors for oral ED treatments in April broke out as follows: Cialis, 19 percent; Levitra, 14 percent; and Viagra, 67 percent.⁹ "The early success of Cialis in the U.S. is similar to the trend we saw when it first became available in other countries. Cialis has claimed market shares of 19 percent to 39 percent across Europe, and even higher in some other markets," said Leonard Blum, vice president of marketing, ICOS Corporation. In the first quarter of 2004, Cialis achieved \$108 million in global sales. More than two million men around the world have been treated with Cialis since its first introduction globally last year.

"For us, the number of Cialis prescriptions written by urologists is one of the most important indicators of future trends. Urologists are the experts in treating ED. We expected that urologists would be the quickest adopters of Cialis, and the data

suggest that these specialists, like their peers overseas, are making Cialis their preferred treatment," said Blum.

Benefits of Cialis

Cialis is changing the way doctors and patients think about treating ED by offering two important benefits: a 36-hour window of opportunity for intimacy and the ability to take the tablet on an empty stomach or with a meal, without concern that high-fat food will reduce the absorption of the medicine.

"What the marketplace tells us is that men and their partners are truly taking advantage of the benefits of Cialis," said Matt Beebe, U.S. brand team leader for Cialis, Lilly ICOS LLC. "Men can take Cialis Friday evening and choose the moment for romance as late as Sunday morning. Because Cialis works for up to 36 hours, it allows a man and his partner to relax, forget about planning intimacy and let it happen when the moment is right for them."

About Cialis

Cialis, approved by the FDA in November 2003 for the treatment of erectile dysfunction, is the only oral ED treatment shown to improve erectile function up to 36 hours in most men. Cialis can be taken without regard to food. The absorption of Cialis is not reduced by food, including high-fat foods. Cialis is currently available in more than 60 countries, including Australia, Brazil, Mexico, Canada, the United States and countries throughout Europe. More than two million patients worldwide have been treated with Cialis since its first introduction in February 2003.

Cialis is available by prescription only and is not for everyone. Men taking nitrates, often used for chest pain, or certain alpha-blockers for prostate problems or high blood pressure, should not take Cialis. Such combinations could cause a sudden, unsafe drop in blood pressure.

Men should discuss their health status with their doctors to ensure Cialis is right for them and that they are healthy enough for sexual activity.

The most common side effects with Cialis were headache, upset stomach, delayed backache and muscle ache. Although rare, men who experience an erection for more than four hours should seek immediate medical attention. Men should not drink alcohol in excess with Cialis. Cialis studies were not designed to assess multiple intercourse attempts after a single dose.

For full patient information, visit www.cialis.com.

About ED

ED is defined as the consistent inability to attain and maintain an erection sufficient for sexual intercourse. ED affects an estimated 152 million men and their partners worldwide.¹⁰ Experts believe that 80 - 90 percent of ED cases are related to a physical or medical condition, like diabetes, cardiovascular diseases, and prostate cancer treatment, while 10 - 20 percent are due to psychological causes.^{11,12} In many cases, however, both psychological and physiological factors contribute to the condition.¹³

About Lilly ICOS LLC

Lilly ICOS LLC, a joint venture between ICOS Corporation and Eli Lilly and Company, developed tadalafil for the treatment of erectile dysfunction.

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 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.

ICOS Corporation, a biotechnology company, is dedicated to bringing innovative therapeutics to patients. Headquartered in Bothell, Wash., ICOS is marketing its first product, Cialis (tadalafil), for the treatment of erectile dysfunction. ICOS is working to develop treatments for serious unmet medical conditions such as chronic obstructive pulmonary disease, cancer and inflammatory diseases.

B-roll is available via satellite, C-band feed:

WEDNESDAY, JUNE 2, 10:30 - 11:00 AM EDT C-Band, IA 6, Tr. 21, DL 4120

WEDNESDAY, JUNE 2, 13:15 - 13:45 PM EDT C-Band, IA 5, Tr. 23, DL 4160

THURSDAY, JUNE 3, 13:00 - 13:30 PM EDT C-Band, IA 5, Tr. 14, DL 3980

Except for historical information contained herein, this press release contains 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 the management of ICOS and Lilly. Investors are cautioned that matters subject to forward-looking statements involve risks and uncertainties, including economic, competitive, governmental, technological, legal and other factors discussed in the two companies' respective filings with the Securities and Exchange Commission, which may affect the business and prospects of the two companies and Lilly ICOS. Results and the timing and outcome of events may differ materially from those expressed or implied by the forward-looking statements in this press release. More specifically, there can be no assurance that Cialis will achieve commercial success or that competing products will not pre-empt market opportunities that might exist for the product.

References

1. Cialis® is a registered trademark of Lilly ICOS LLC. All other trademarks are the property of their respective owners.
2. Viagra® is a registered trademark of Pfizer, Inc.
3. The term "new treatment initiations" indicates when a physician writes out a new prescription for patients never before treated, and for patients switching from one product to another. This does not include prescriptions conveyed to pharmacies by phone or refills of existing prescriptions. In this release, new treatment initiations describes data from ImpactRx only.
4. ImpactRx™ has a panel of high prescribing physicians that recorded information on patient visits (patient identity is non-identifiable), including diagnosis and treatment. ImpactRx data includes new prescriptions written and refills but not prescriptions conveyed by phone. ImpactRx records information from the physician perspective and not what happens at the pharmacy.
5. Levitra® is a registered trademark of Bayer/GSK.
6. ImpactRx, "PromoLink," April 2004.
7. Computed from IMS NPA Plus™, April 2004. IMS numbers vary from those of ImpactRx primarily because IMS data represent aggregated pharmacy sales, reflecting what is filled at the pharmacy including new prescriptions for continuing users and prescriptions called in by phone.
8. "The Three PDE 5 Inhibitors Sildenafil, Tadalafil And Vardenafil - Results Of A Comparative Preference Trial In 222 Patients With Erectile Dysfunction," Hartmut Porst, et. al., presented in poster session at American Urological Association Annual Meeting, May 2004.
9. Computed from IMS NPA Plus™, April 2004.
10. Aytac Ia, McKinlay JB, Krane RJ. The Likely Worldwide Increase in Erectile Dysfunction Between 1995 and 2025 and Some Possible Policy Consequences. *BJU Int* 1999; 84: 50-56.
11. Shabsigh, R. (2002). *Back To Great Sex: Overcome ED and Reclaim Lost Intimacy*. New York: Kensington.
12. Diseases and Conditions: Impotence, <http://www.impotence.org/FAQ/index.asp> . Data accessed 11.20.03
13. Lue, Tom F. Erectile Dysfunction. *N Engl J Med* 2000; 342: 1802-1813



Cialis, 20 mg Dosage