



December 8, 2004

## **Lilly Launches Online Clinical Trial Registry at [www.lillytrials.com](http://www.lillytrials.com): Company to Publish Results for All Lilly Marketed Products and Initiation of All Phase II - IV Clinical Trials**

### **NewsMaker Forum to provide perspective on the challenges facing the industry as it moves to publish all clinical trial data**

A **replay** of Lilly's **NewsMaker Forum** media briefing conference call discussing Lilly's online clinical trial registry is **available through Tuesday, December 14, 2004**.

INDIANAPOLIS, Dec 8, 2004 /PRNewswire-FirstCall via COMTEX/ -- Eli Lilly and Company (NYSE: LLY) today will announce the launch of its publicly available clinical trial registry, [www.lillytrials.com](http://www.lillytrials.com), which will post the results from all Phase I through Phase IV clinical trials of Lilly's marketed products. Additionally, the company will post information on the initiation of all Lilly-sponsored Phase II through Phase IV clinical trials via the web site registry. A demonstration of Lilly's new registry web site will be made available to reporters during the company's NewsMaker Forum, a media briefing held today via conference call, which also will include a discussion and commentary on the topic of industry clinical trial registries.

#### **Listen to Conference Call Replay**

**Reporters** can access the media briefing conference call by dialing:

- Domestic Caller Dial-In Number: **(800) 475-6701**
- International Caller Dial-In Number: **(320) 365-3844**
- Access Code: **759029**

The Lilly registry will be the most comprehensive effort to date, by either a public or private entity, to publicly disclose clinical trial information," said Dr. Alan Breier, vice president and chief medical officer, Eli Lilly and Company. "We believe the Lilly registry will become a tremendous resource for physicians and health care providers seeking important information about clinical research involving Lilly medicines."

Breier added that [www.lillytrials.com](http://www.lillytrials.com) is populated with nearly one-half of the data the company has committed to make publicly available. Some additional results are complete, but are not currently being disclosed due to pending publication. Other outstanding data is being gathered and inputted to fully populate the registry web site by no later than July 2005.

NewsMaker Forum guests include the following:

**Alan Breier, M.D.**, is vice president and chief medical officer for Eli Lilly and Company. Trained in psychiatry at Yale University, Dr. Breier is a practicing physician and adjunct professor of psychiatry at Indiana University School of Medicine in Indianapolis. Prior to coming to Lilly, he was a tenured scientist at the National Institute of Mental Health, where he established a research program investigating the causes of schizophrenia and development of new treatments for the illness. He has published more than 200 scientific articles and has served on the editorial boards of several scientific journals.

**Michael Smith** is the manager of business operations for Lilly's global medical team. Mr. Smith has overseen the project team that developed [www.lillytrials.com](http://www.lillytrials.com). As a part of the NewsMaker Forum, Mr. Smith will facilitate a demonstration of the web site.

The NewsMaker Forum is a program sponsored by Lilly corporate communications to provide timely and relevant information for the media from top experts, inside and outside the company, who offer their perspectives on important health-related topics.

More information about [www.lillytrials.com](http://www.lillytrials.com)

#### **What results Lilly will publish on [www.lillytrials.com](http://www.lillytrials.com)**

For each clinical trial of its marketed products, the company will publicly disclose the results corresponding to the study's predefined primary and secondary outcome measures that are specified in the study protocol, as well as additional safety and efficacy results that affect patient care and the clinical use of Lilly products. Results that do not support the hypothesis being tested or that are contrary to the expected outcome will be disclosed. Additionally, Lilly will post a comprehensive description of the trial design and methodology for each study.

**Which initiated clinical trials will be registered on [www.lillytrials.com](http://www.lillytrials.com)**

A listing of all Phase II, III, and IV clinical trials will be posted on the registry at the initiation of each trial using a unique numerical identifier, trial descriptor, phase, trial start date, projected end date and trial status. When a trial is completed and the drug is commercially available, the results of the trial will be affixed to its identifier. Lilly already posts serious and life-threatening studies to the government's web site, [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Beginning next year, the company will populate the government site with all Lilly-sponsored Phase II, III, and IV clinical trials, regardless of the disease or condition being studied.

**When Lilly will disclose results on [www.lillytrials.com](http://www.lillytrials.com)**

For Phase I, II and III studies, Lilly will disclose clinical trial results when a drug's indication is approved and the drug is commercially available. Additionally, Phase III trial results for secondary indications of marketed drugs that fail to support the hypothesis being tested or which are contrary to the intended outcome will be disclosed as soon as possible after the data analysis is completed but not later than one year after the trial is completed. Phase IV trial results will also be disclosed as soon as possible after the data analysis is complete but no later than one year after the trial is finished. For studies that are under review by a peer-reviewed journal that prohibits prepublication disclosure of results, the results will be posted on the registry at the time of publication.

**How Lilly will disclose results**

In all cases, Lilly will disclose clinical trial results on [www.lillytrials.com](http://www.lillytrials.com), a publicly available online registry. Lilly also will seek to disclose results through a peer-reviewed medical journal, subject to the discretion of the journal editors. The company will commit to providing a reference in the clinical trial registry for study results that are disclosed in a peer-reviewed journal. In addition, Lilly's clinical trial results may be disclosed through presentations or abstract submissions at professional scientific meetings.

**Timeline and audit for [www.lillytrials.com](http://www.lillytrials.com)**

Implementation of these standards will begin with all clinical trials for marketed products that were completed after July 1, 2004. In addition, the registry will be populated retrospectively with results of core efficacy and safety registration trials of marketed compounds approved since July 1, 1994.

The company will assign an independent third party to audit and verify adherence by Lilly to these standards of disclosure.

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](http://www.lilly.com). C-LLY