January 13, 2005

Lilly Launches Public Outreach Initiative to Correct Allegations About Company and Prozac

INDIANAPOLIS, Jan 13, 2005 /PRNewswire-FirstCall via COMTEX/ -- Eli Lilly and Company (NYSE: LLY) today announced its plans to correct inaccurate statements circulating in the news media based on a collection of random papers anonymously sent to the British Medical Journal (BMJ). Lilly has posted a detailed explanation of those papers in question on its website and has published an open letter to patients in leading U.S. newspapers to state its case.

"While it is important that we correct false assertions about how Lilly manages its data, it is even more important to set the record straight for patients who rely on our medicines for their daily well-being," said Sidney Taurel, chairman, president and chief executive officer. "It is simply wrong to suggest that information on Prozac was ever missing or that important research data on the benefits and possible side effects of the drug were not available to doctors and regulators," said Taurel.

In Lilly's open letter to the public, Taurel states: "At Lilly, we're concerned that the BMJ story, and misleading reports about it in other media, have needlessly spread fear among patients who take Prozac. But the best thing that we can do is to seize this as an opportunity to improve everyone's access to information about Prozac - one of the most widely studied therapies in the entire history of medicine."

Data Tables in Documents Continue to Be Misrepresented

The article published by the BMJ and subsequent articles from various media contain false allegations regarding disclosure about important Prozac safety information as well as misleading and scientifically invalid conclusions about Prozac data.

"Lilly has always been forthcoming with safety data. This particular information has been shared with regulators and publicly discussed by experts, with conclusions supporting Prozac's safety," said Alan Breier, M.D., vice president and chief medical officer, Eli Lilly and Company. "We are confident that there is more known about Prozac after two decades of rigorous study than any other comparable medication," he added.

Erroneous conclusions drawn from tables comprised of spontaneous adverse event data (a reporting system for a particular drug comprised of adverse events occurring in people taking the drug) in the documents obtained by BMJ are at the heart of the data misrepresentations and reflect the fundamental problem of the BMJ reporting on statistical information without providing scientific context. Specifically, the media reports stating that Prozac is 12 times more likely to cause suicide than other, older antidepressants is patently false and not supported by clinical trial data.

"A worrisome outcome from these inaccurate reports would be for patients who are stable on medication to stop treatment unnecessarily, which has the

potential of undoing clinical progress and setting back patients in their illness," said Doctor Breier.

Among the documents provided to BMJ are charts created by a hired expert for plaintiffs' attorneys, whose own admission in legal testimony concluded that the data contained in these charts do not show that Prozac causes suicidality or violence.

These very data were initially presented by the FDA to evaluate the safety of Prozac in 1991 to an advisory committee comprised of external experts. The FDA advisory committee voted unanimously in support of Prozac's safety.

Spontaneous adverse event reports have been the subject of significant research in the scientific community, and it is widely agreed that only controlled clinical trials can achieve valid comparisons between medications. Drawing conclusions about causality from spontaneous adverse event reports is invalid, given several important limitations. The limitations include the nature of voluntary reporting, variables such as other drugs a patient may be taking and duplicate reporting of the same adverse event from more than one source (e.g., pharmaceutical company, patient, physician, and pharmacist). Reports on suicide attempts and suicidal ideation, in particular, are problematic because each case represents an individual with varying degrees of illness, treatment and support, making it difficult to understand the nature of the event.

Prozac has helped to significantly improve millions of lives and it has been prescribed for more than 54 million people worldwide.

Lilly Interested in Driving Toward Solution

To demonstrate Lilly's transparency, the company is in the process of talking to all parties - the FDA, Congressman Hinchey, and the BMJ, in an effort to resolve the situation. Lilly is committed at the highest level to ensuring that all parties, and most importantly, our customers, are satisfied with those answers.

Additionally, Lilly is calling on the BMJ to make the full documents available to media and other interested parties. Lilly obtained the documents from the office of Congressman Maurice Hinchey (D-NY).

The detailed explanation of the inaccurately alleged "missing documents" can be found at lilly.com. Patients with questions concerning Prozac or other Lilly medicines may call Lilly's customer service line at 1-800- LILLYRX (1- 800-545-5979).

Lilly believes in full and appropriate disclosure of clinical trial data. Lilly recently launched its clinical trial registry database, www.lillytrials.com, which was noted as being among the most comprehensive databases to date of its kind in the industry. Lilly has already populated the website with pediatric data for Prozac and is continuing the process to populate the website. Lilly is committed to the health and safety of all patients being treated with its medicines and to ensuring health care professionals and families have the information they need to make informed treatment decisions.

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. C-LLY

Things to Know About PROZAC

PROZAC is available by prescription only. A rash can be a sign of a serious medical condition. See your doctor immediately if you develop a rash while taking PROZAC. Also, you should not take PROZAC at the same time as or within 2 weeks if stopping a type of antidepressant medication known as an MAO inhibitor. Don't take MAO inhibitors for at least 5 weeks after stopping PROZAC.

Thioridazine should not be administered with PROZAC or within a minimum of 5 weeks after PROZAC has been discontinued.

Prozac® Weekly™, PROZAC, generic versions of PROZAC, and Sarafem® contain the same active ingredient, fluoxetine hydrochloride. Some people experience side effects like nausea, difficulty sleeping, drowsiness, anxiety, nervousness, weakness, loss of appetite, tremors, dry mouth, sweating, decreased sex drive, impotence, or yawning. Most of these tend to go away within a few weeks of starting treatment and, in most cases, aren't serious enough to cause people to stop taking PROZAC.

You should also talk to your doctor if you are pregnant or are nursing.

In addition, you, your family and other caregivers should be aware of the following information: Depression, as a disease, can be associated with periods when the symptoms can worsen and thoughts of suicide can emerge. Patients and their families should watch for these as well as for anxiety, agitation, panic, difficulty sleeping, irritability, hostility, aggressiveness, impulsivity, restlessness, or over excitement and hyperactivity. Call the doctor if any of these are severe or occur suddenly. Be especially observant at the initiation of antidepressant drug therapy and when there is a change in dose.

Tell your doctor if you have ever been told you had Bipolar Disorder ("Manic Depression") or have had a "manic" or "psychotic" episode.

For more information, including full Prescribing Information, please visit www.prozac.com, or call 1-800-LillyRX.

Morry Smulevitz, +1-317-651-5567, or Angela Sekston, +1-317-276-5046, both of Eli Lilly and Company