Lilly Announces Termination of AIR Insulin Program

INDIANAPOLIS, March 7, 2008 /PRNewswire-FirstCall via COMTEX News Network/ -- Eli Lilly and Company (NYSE: LLY) today announced the termination of development of its AIR(R) Insulin program, which was being conducted in partnership with Alkermes, Inc. The program has been in phase III clinical development as a potential treatment for type 1 and type 2 diabetes. The company noted that this decision is not a result of any observations during AIR Insulin trials relating to the safety of the product, but rather was a result of increasing uncertainties in the regulatory environment, and a thorough evaluation of the evolving commercial and clinical potential of the product compared to existing medical therapies.

"This decision, though difficult, is the right one to make at this time," commented John Lechleiter, Ph.D., Lilly president and chief operating officer. "Over the past several months we have conducted a thorough review of all aspects of our efforts to develop our AIR Insulin product and have now made the decision that it would be inappropriate for the company to continue development activities in connection with this project. Without the prospect of a new drug application, keeping the patient foremost in mind, it would not be consistent with our medical principles to continue the clinical trials. As a result, we are now beginning the process of halting our ongoing clinical studies and transitioning the AIR Insulin patients in these studies to other appropriate therapies. We wish to reassure patients currently receiving AIR Insulin in our ongoing clinical trials that they should have no health or safety concerns about continuing to use AIR Insulin during their transition to other well-established diabetes therapies."

Steven M. Paul, M.D., executive vice president, science and technology for Lilly, added "While we are confident in our decision, we also recognize the disappointment of those patients who saw the potential benefit of AIR Insulin. As a leader in diabetes care, we remain committed to our mission to develop innovative, beneficial and cost-effective treatments for diabetic patients. It is also important to emphasize that our decision is not due to any safety concerns observed by Lilly or raised by the independent data safety monitoring board during our development of AIR Insulin."

Lilly is in the process of contacting the clinical investigators conducting the current AIR Insulin clinical trials. Subject to protocols, the trials will be halted and the patients currently enrolled will be moved to other insulin therapy under the supervision of their physicians. In the U.S., Lilly will implement a patient assistance program to provide current clinical trial patients with appropriate financial support to fund their medications and diagnostic supplies through the end of 2008. Based upon further analysis, the company may also pursue a similar program in other regions.

As a result of the decision to terminate the development of AIR Insulin, Lilly will recognize a first-quarter 2008 charge to earnings related to the impairment of Lilly assets, as well as wind-down costs associated with the termination of clinical trials and certain development activities, and costs associated with the patient assistance program. The exact amount of the charge has not yet been determined, but is estimated to be in the range of $90 million to $120 million, or $0.05 to $0.07 per share. Lilly's pro forma adjusted earnings per share guidance remains unchanged at $3.85 to $4.00. On a reported basis, including the charge related to the termination of the AIR Insulin program, as well as the previously announced charge related to the BioMS in-licensing, Lilly now expects 2008 earnings per share to be in the range of $3.73 to $3.90. See the reconciliation table below for further detail.

Reconciliation of 2008 Earnings Per Share Expectations:

	2008 Expectations	2007 Results	% Growth
E.P.S. (reported)	$3.73 to $3.90	$2.71	
Eliminate estimated charge related to asset impairments and certain wind-down costs associated with the termination of the AIR Insulin program	.05 to .07		
Eliminate estimated in-process			

research and development charge associated with BioMS Medical in-licensing	.05		
Eliminate asset impairments, restructuring and other special charges	-	.15	
Eliminate charge for a reduction in expected insurance recoveries	-	.06	
Eliminate in-process research & development charges associated with ICOS, Hypnion, and Ivy acquisitions and OSI, MacroGenics and Glenmark in-licensing transactions	-	.63	
Include pro forma as if the ICOS acquisition was completed on January 1, 2006	-	(.01)	
E.P.S. (pro forma adjusted)	$3.85 to $4.00	$3.54	9% to 13%

About Lilly

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. P-LLY

This press release contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. There are significant risks and uncertainties in pharmaceutical research and development. There can be no guarantees with respect to pipeline products that the products will receive the necessary clinical and manufacturing regulatory approvals or that they will prove to be commercially successful. The company's results may also be affected by such factors as competitive developments affecting current products; rate of sales growth of recently launched products; the timing of anticipated regulatory approvals and launches of new products; regulatory actions regarding currently marketed products; other regulatory developments and government investigations; patent disputes and other litigation involving current and future products; the impact of governmental actions regarding pricing, importation, and reimbursement for pharmaceuticals; changes in tax law; asset impairments and restructuring charges; acquisitions and business development transactions; and the impact of exchange rates. For additional information about the factors that affect the company's business, please see the company's latest Form 10-K filed February 2008. The company undertakes no duty to update forward-looking statements.

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