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MannKind Addresses Pfizer's Announcement Regarding Exubera

VALENCIA, Calif., April 10 /PRNewswire-FirstCall/ -- MannKind Corporation (Nasdaq: MNKD) released the following statement in response to the announcement by Pfizer Inc. that over the course of Exubera's clinical trial program, 6 of the 4,740 patients treated with Exubera developed lung cancer, although Pfizer concluded that there were too few cases to determine whether this observation was related to Exubera. According to Pfizer's "Dear Doctor" letter, Exubera remains a safe and effective medication. It is important to note that each of the patients affected had a history of cigarette smoking, a known, major risk factor for lung cancer. Although the sugar-based Exubera formulation did have a small but statistically significant impact on pulmonary function, we are not aware of any specific carcinogenicity studies of Exubera to evaluate the potential of cancer risk.

In contrast, the safety profile of Technosphere[®] Insulin has been examined in an extensive pre-clinical program, including a two-year carcinogenicity study in rats, in which we observed that Technosphere[®] Insulin and Technosphere[®] particles alone were well tolerated after daily inhalations for 104 consecutive weeks. There were no indications that our product or the carrier material alone had carcinogenic potential or caused cellular proliferation in the lungs. We also recently completed a six-month carcinogenicity study in transgenic mice that are prone to cancer. We found no macroscopic indications of carcinogenicity in animals treated with Technosphere[®] Insulin or Technosphere[®] particles for 26 consecutive weeks. The analysis of the histology data is in progress and will be completed later this quarter.

Our Technosphere[®] Insulin clinical program is designed to provide data on safety and efficacy in a broad group of patients with diabetes. We have not observed a higher incidence of lung cancer in Technosphere[®] Insulin patients than that expected in the general population. Our independent Data Safety Monitoring Board (DSMB) regularly reviews all potential safety issues with our clinical trials and has consistently recommended that the trials continue without changes. Given Pfizer's announcement, the DSMB met again yesterday and found that on the basis of the current information our trials could continue.

Ensuring patient safety is always our primary concern. To date with our product, we have seen no adverse effects on the measures of pulmonary function that have been reported to occur with Exubera. We are working closely with the DSMB and regulatory agencies in order to understand the implications of the Exubera data.

Additionally, given the current market sentiment, we have decided to suspend partnership discussions. At this time, we believe that we will be unable to achieve an appropriate valuation for Technosphere Insulin until Phase 3 data are available that confirm our belief in the safety and efficacy of Technosphere Insulin.

About MannKind Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the discovery, development and commercialization of therapeutic products for diseases such as diabetes and cancer. Its lead product, the Technosphere[®] Insulin System, is currently in phase 3 clinical trials in the United States, Europe and Latin America to study its safety and efficacy in the treatment of diabetes. For more information on MannKind Corporation and its technology, visit <http://www.mannkindcorp.com>.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding a partnership for the commercialization of Technosphere[®] Insulin. Words such as "believes", "anticipates", "plans", "expects", "intend", "will", "goal", "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon MannKind's current expectations and involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the progress, timing and results of clinical trials, whether results of further clinical trials of Technosphere[®] Insulin will reveal safety concerns, whether the clinical data regarding Technosphere[®] Insulin will support regulatory approval, difficulties or delays in seeking or obtaining regulatory approval, whether MannKind will be able to enter into and maintain a collaboration with a pharmaceutical partner for commercialization of Technosphere[®] Insulin and its other peptide hormone drug candidates on attractive terms for MannKind if at all, and other risks detailed in MannKind's filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the year ended December 31, 2007 and periodic reports on Form 10-Q and Form 8-K. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. All forward-looking statements are qualified in their entirety by this cautionary statement, and MannKind undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this press release.

SOURCE MannKind Corporation

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