MannKind Corporation Response to Recent Market Events

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MannKind Corporation Response to Recent Market EventsVALENCIA, Calif., March 10 /PRNewswire-FirstCall/ -- MannKind Corporation (Nasdaq: MNKD) today issued the following statement in response to recent market events:

MannKind is absolutely committed to the continued development of its lead development product, Technosphere® Insulin. We use our small, patient-friendly Medtone® inhaler to deliver Technosphere® Insulin to patients with diabetes in a way that much more closely matches the pattern of insulin secretion seen in people without disease. MannKind believes that the resulting efficacy and safety profile is unique and clearly differentiated from all existing diabetes treatments. To achieve normal glucose control, it is necessary to independently address both mealtime and fasting glucose. We believe Technosphere® Insulin is the only therapy that separately and independently lowers prandial glucose excursions, and that it will thus offer an important benefit to many patients with this devastating disease.

MannKind recognizes that in order to be successful in today's health care market a product must offer improved efficacy and safety, not just improved convenience. The decisions of Eli Lilly and Company as well as Pfizer and Novo Nordisk to discontinue the development of their inhaled insulin products reinforce this view. None of those products offer any advantages over injectable rapid acting insulin analogs.

By contrast, in clinical trials to date, Technosphere® Insulin has shown important advantages over the treatment that is presently considered to be the most effective meal-time therapy for patients -- rapid-acting insulin analogs. Specifically, Technosphere® Insulin has demonstrated:

A significant reduction in post-prandial glucose excursions, approaching the levels seen in normal people, which are believed to be an important risk factor in the development of complications from the disease.

The ability to achieve comparable levels of overall glucose control compared with present "state of the art" treatment, as measured by HbA1c, which is considered the standard measure of a treatment's effectiveness in diabetes.

A lower risk of hypoglycemia, which is considered to be a major problem for patients using presently available insulins and many oral treatments, limiting their ability to optimally treat their disease.

No weight gain and even weight loss in patients treated with Technosphere® Insulin, in contrast to the weight gain that is usually considered a major downside of insulin therapy for many patients.

No need for complex meal titration, as utilized in our studies to date, significantly simplifying treatment and reducing the training typically needed for insulin therapy.

No adverse effect on the measures of pulmonary function that have been reported to occur with other inhaled insulins.

Even with these advantages over existing insulin therapy, MannKind understands that physicians and regulatory agencies are cautious about a new route of administration. For this reason, MannKind is conducting a very robust clinical trial program involving more than 5,000 patients with diabetes, which it determined is consistent with the FDA's recently released guidance for the development of drugs to treat diabetes. As part of this program, a 2,050-patient, two-year pulmonary safety trial will conclude later this year; this trial was recently recognized by the American Association of Respiratory Care as setting new quality standards in the conduct of clinical studies. In the interim, all of MannKind's clinical trials are monitored by an independent data safety monitoring board that meets at regular intervals to review safety data. To date, the data safety monitoring board has fully endorsed continuation of the trials as planned.

MannKind has also undertaken a more comprehensive examination of the toxicology profile of Technosphere® Insulin than has been reported for any other inhaled insulin. Last year, MannKind completed a two-year carcinogenicity study in rats in which Technosphere® Insulin, and large doses of Technosphere® particles alone, were well tolerated after daily inhalations for 104 consecutive weeks. There were no indications in these studies that either Technosphere® Insulin or Technosphere® particles alone had any carcinogenic potential or caused any cellular proliferation in the lungs. MannKind also recently completed a six-month carcinogenicity study in transgenic mice, finding no macroscopic indications of carcinogenicity in animals given daily subcutaneous injections of Technosphere® Insulin or Technosphere® particles for 26 consecutive weeks. In addition, MannKind plans to submit data from over 100 preclinical studies supporting the safety of our product, the vast majority of which have already been completed.

The pharmacokinetic profile of Technosphere® Insulin sets it apart from all other insulin products. The large surface area of the lung provides unique access to the circulatory system, but the sugar-based carriers used by others simply cannot convey insulin to the bloodstream any faster than that achieved by a subcutaneous injection of a rapid-acting insulin analog. In contrast, the pH-sensitive Technosphere® particles dissolve upon contact with the lung surface, releasing insulin monomers that rapidly enter the bloodstream. As described in recent publications in the Journal of Diabetes Science and Technology, MannKind's Technosphere® Insulin achieves peak insulin levels within 12-14 minutes of administration, effectively mimicking the release of meal-time insulin observed in healthy individuals, but which is absent from patients with diabetes. MannKind believes that by mimicking the normal physiologic release of meal-time insulin, Technosphere® Insulin will be positioned as the only insulin therapy that effectively addresses post-prandial glucose excursions.

MannKind is only beginning to explore the opportunities associated with the ability to deliver a peptide hormone in ways that mimic normal hormone physiology. The data from MannKind's pivotal Phase 3 trials of Technosphere® Insulin will start to become available in the third quarter of 2008. In the meantime, in a Phase 1 trial of MKC253, another Technosphere®-based product, blood levels of GLP-1 were observed to peak within three minutes of administration, which may mimic the natural short pulse of GLP-1 that is produced in a healthy individual in response to glucose ingestion. Following administration of MKC253, study subjects experienced a dose-dependent increase in insulin levels and a decrease in glucose levels. Even at the highest doses of MKC253, subjects did not report any sweating, nausea or vomiting whereas those side effects are associated with the use of injectable GLP-1 products that do not mimic the natural, pulsatile feature of this hormone. These data will be presented in detail at the upcoming meeting of the American Diabetes Association.

MannKind believes that a significant need exists for products that offer efficacy and safety advantages in the delivery of peptide hormones. MannKind is committed to continuing the clinical development of Technosphere® Insulin and MKC253. A third peptide hormone for the treatment of obesity is in preclinical development. Currently, MannKind has sufficient financial resources to fund these programs and others through the end of 2009. It is MannKind's intention to bring these treatments to patients in collaboration with a leading pharmaceutical partner who shares a commitment to improving the lives of people with diabetes and who understands the difference between MannKind's products and other diabetes therapies on the market today.

Selected References

Journal of Diabetes Science and Technology 2008; 2(1):47-57. Journal of Diabetes Science and Technology 2008; 2(2):205-212.

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 related to the positioning of Technosphere Insulin and differentiating it from other insulins. 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 show efficacy and safety that clearly differentiate it from existing diabetes compounds, whether the ability of Technosphere® Insulin to mimic the normal physiologic release of meal-time insulin will provide treatment advantages that will support regulatory approval and, if approved, physician and patient adoption, 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, 2006 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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