



New Findings Show Bioequivalence, Ease-of-Use and Efficiency of MannKind's Drug Delivery Platform

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VALENCIA, Calif., Nov 15, 2010 (BUSINESS WIRE) -- MannKind Corporation (Nasdaq: MNKD) unveiled new data on its drug delivery, device and particle technologies demonstrating the bioequivalence, ease of use and efficiency of the company's novel platform. The proprietary technology, founded on the company's expertise in inhaled drug development, device engineering and powder formulation performance, was evaluated in four separate studies presented at the 10th annual meeting of the Diabetes Technology Society in Bethesda, Maryland, November 12-13. The first application of this technology, the novel, ultra rapid-acting insulin AFREZZA[®] (insulin human [rDNA origin]), is currently under review by the U.S. Food and Drug Administration (FDA) and has a PDUFA date of December 29, 2010.

"We are excited about the progress of AFREZZA, our first program to utilize this technology, and we look forward to applying the platform to other products where there is a medical benefit," said Dr. Peter Richardson, MRCP, corporate vice president and chief scientific officer for MannKind Corporation.

Findings of the studies are as follows:

- Bioequivalence of the inhaler used in the Phase 3 clinical trials for AFREZZA (MedTone[®]) and the next-generation delivery system planned to be marketed with AFREZZA (Gen2) was demonstrated using two separate methods of analysis (Roche ECLIA and RIA) with all parameters and dose groups passing the bioequivalence criteria.
- An additional study also demonstrated the bioequivalence of the Gen2 device and the clinical inhaler. Based on the results, insulin exposures when using either system to administer AFREZZA insulin were bioequivalent while dose-equivalence between two 10 U cartridges and one 20 U cartridge of AFREZZA inhalation powder was also achieved.
- A third trial, designed to evaluate the bioavailability of insulin delivered using the two inhalers and the acute effects on lung functions immediately after inhalation, found no clinically meaningful acute FEV1 changes observed from pre- to post-inhalation over a two-hour period. With the Gen2 delivery system, acute FEV1 changes after the administration of AFREZZA were minimal and consistently smaller than those observed with the MedTone inhaler.
- Additional data showed that children as young as 4 years of age can successfully handle, assemble and operate the Gen2 device.

All presented posters are available on the MannKind website (www.mannkindcorp.com):

- Acute Pulmonary Effects of Technosphere[®] Insulin Inhalation Powder Administered Using a Gen2B Inhaler Compared to a MedTone[®] C Inhaler
- Bioequivalence and Dose Proportionality of AFREZZA[®] Inhalation Powder Administered Using a Gen2 Inhaler Compared to the MedTone[®] Inhaler
- The Relationship Between Two Insulin Assays Used to Determine Bioequivalence and Dose Proportionality of AFREZZA[®] Insulin Administered Using a Gen2 Inhaler Compared to a MedTone[®] Inhaler: Simulation of Clinical Trials and Actual Trials
- Handleability and Characterization of Inhalation Profiles Using the Gen2 Delivery System in a Pediatric Population

About MannKind Corporation

MannKind Corporation (Nasdaq: MNKD) focuses on the discovery, development and commercialization of therapeutic products for patients with diseases such as diabetes and cancer. Its diabetes pipeline includes AFREZZA[®] and MKC253. MKC253 is currently in phase 1 clinical trials. In March 2009, MannKind submitted a NDA to the FDA requesting approval of AFREZZA for the treatment of adults with type 1 or type 2 diabetes for the control of hyperglycemia. In March 2010, MannKind received a Complete Response letter to this NDA from the FDA, requesting additional information. In July 2010, the FDA accepted MannKind's reply to the Complete Response letter and set a PDUFA action date of December 29, 2010. Other products in MannKind's pipeline include the cancer immunotherapy platform MKC1106, which is currently in phase 2 clinical trials. MannKind maintains a website at www.mannkindcorp.com to which MannKind regularly posts copies of its press releases as well as additional information about MannKind. Interested persons can subscribe on the MannKind website to e-mail alerts that are sent automatically when MannKind issues press releases, files its reports with the Securities and Exchange Commission or posts certain other information to the website.

SOURCE: MannKind Corporation

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