MannKind Corporation

FDA UPDATES AFREZZA® PRESCRIBING INFORMATION

Now Includes New Data Regarding Rapid Onset of Activity and Duration of Effect

WESTLAKE VILLAGE, California (Globe Newswire) – October 2, 2017 – MannKind Corporation (Nasdaq and TASE: MNKD) today announced that the U.S. Food & Drug Administration (FDA) has approved an update to the Afrezza prescribing information to include new clinical data that was presented at the American Diabetes Association's 76th Scientific Sessions in June 2016. Afrezza (insulin human) inhalation powder is approved by the FDA to improve glycemic control in adult patients with type 1 and type 2 diabetes mellitus. It is the only inhaled rapid-acting mealtime insulin available in the United States. Afrezza is dosed at the beginning of a meal and begins to appear in the blood in approximately one minute[1].

Key highlights of the label update:

1) Inclusion of study data that describe the time-action profile by dosage strength, showing first measurable effect starts in approximately 12 minutes, peak effects occur approximately 35 to 45 minutes after dosing and return to baseline after approximately 1.5 to 3 hours for the 4 and 12 unit cartridges respectively.
2) Clarity on “Starting” and “Adjusting” mealtime dose.
3) Updated pregnancy and lactation section to conform to current FDA label guidance.

"These data articulate the rapid-acting nature of Afrezza to address post-prandial hyperglycemia, setting it apart from other mealtime options available to help patients maintain greater control over their blood glucose levels,” said Satish Garg, MD, MBBS, DM — Barbara Davis Center for Diabetes (BDC) – University of Colorado.

Details of the label update:

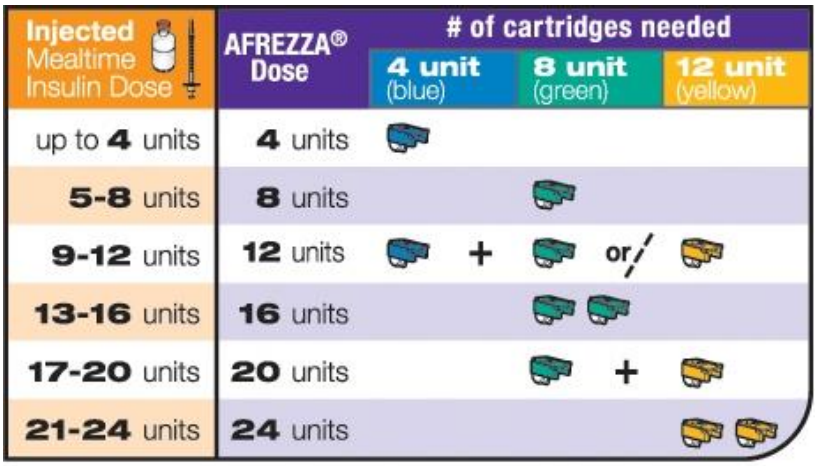
1) Clinical Pharmacology (Section 12): The basis of this label change comes from a randomized, controlled, six-treatment, crossover dose-response study comparing Afrezza to the rapid-acting insulin analog, lispro, in 30 patients with type 1 diabetes. The data highlighted below demonstrates the importance of understanding the time to peak effect and time for effect to return to baseline.

Parameter for Insulin Effect of Available Cartridge Forms	AFREZZA 4 units	AFREZZA 12 units
Time to first measurable effect	~12 minutes	~12 minutes
Time to peak effect	~35 minutes	~45 minutes
Time for effect to return to baseline	~90 minutes	~180 minutes

2) Dosage and Administration (Section 2): The **Dosing Information** section has been updated with “Step 1” to inform how patients on injected mealtime insulin should initially be dosed on Afrezza (Figure 1). Additionally, “Step 2” was added to highlight that mealtime

dose adjustments may be required based on the individual metabolic needs and glycemic control goals.

Figure 1. Mealtime AFREZZA Starting Dose Conversion Table



3) Use in Specific Populations (Section 8): The **Pregnancy** and **Lactation** sections of the label have been updated to conform to the current FDA label guidance. These areas have been configured to provide healthcare providers with clearer risk benefit information for informed decision making in these populations.

In conjunction with the approved labeling revision, MannKind received a letter of Fulfillment of Post-Marketing Requirements for PMR 2166-2 and PMR 2166-3, satisfying two of the four post-marketing requirements for Afrezza as described in the 2014 FDA approval letter.

"Available data suggests approximately 70% of people living with diabetes on insulin are not at HbA1c goals of <7% [2]," said Michael Castagna, Chief Executive Officer, MannKind Corporation. "We firmly believe that in order for patients to achieve better HbA1c goals, control of mealtime glucose spikes is critical. This label update supports Afrezza as a unique fast-acting mealtime insulin that provides doctors and patients with the flexibility necessary to help them achieve glycemic control."

About Afrezza

Available by prescription, Afrezza® (insulin human) inhalation powder is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza was studied in over 60 different clinical trials evaluating >3,000 people living with type 1 and type 2 diabetes. Afrezza is covered by many national and regional insurance plans and MannKind offers a savings card that reduces the copay for most commercially insured patients to as little as $15. Afrezza is the only inhaled rapid-acting insulin available today. The inhaled route of delivery is a unique feature that can spare patients from multiple daily mealtime injections, but the true benefit of Afrezza is defined by its rapid time-to-measurable-effect, time-to-peak, and return-to-baseline, all of which allow patients the ability to experience the management of their disease in a different way.

About MannKind Corporation

MannKind Corporation (NASDAQ:MNKD) (TASE:MNKD) focuses on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes

and pulmonary arterial hypertension. MannKind is currently commercializing Afrezza® (insulin human) inhalation powder, the Company's first FDA approved product, in the United States, where it is available by prescription from pharmacies nationwide. MannKind is headquartered in Westlake Village, California, and has a state-of-the-art manufacturing facility in Danbury, Connecticut. The Company also employs field sales and medical representatives across the U.S. For further information, visit www.mannkindcorp.com.

ABOUT DIABETES MELLITUS

Currently, diabetes mellitus affects over 30 million people in the United States, according to the Centers for Disease Control and Prevention[3]. Diabetes mellitus is characterized by the body's inability to regulate levels of blood glucose properly. Insulin, a hormone produced by the pancreas, normally regulates the body's glucose levels, but in people with diabetes mellitus insufficient levels of insulin are produced or the body fails to respond adequately to the insulin it produces. In patients with diabetes, current injected insulins are absorbed into the bloodstream slower than the body's own insulin would be released if the pancreas was healthy.

REFERENCES

(1) Data on file, MannKind Corporation (MKC-TI 142)
(2) Selvin et al. Diabetes Care 2016; 39: e33-e35.
(3) Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. CDC website. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf. Accessed September 2017.

INDICATION

Prescription Afrezza® (insulin human) inhalation powder is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

LIMITATIONS OF USE

Afrezza is not a substitute for long-acting insulin; Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes.

Afrezza is not recommended for the treatment of diabetic ketoacidosis.

Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

IMPORTANT SAFETY INFORMATION FOR AFREZZA

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

- Acute bronchospasm has been observed in patients with asthma and COPD using Afrezza.
- Afrezza is contraindicated in patients with chronic lung disease such as asthma or COPD.
- Before initiating Afrezza, perform a detailed medical history, physical examination, and spirometry (FEV1) to identify potential lung disease in all patients.

Do not use Afrezza if you have chronic lung problems such as asthma or COPD. Do not use Afrezza during a low blood sugar reaction (hypoglycemia). If you are allergic to regular human insulin or any of the ingredients in Afrezza, do not use Afrezza as this may cause a significant and severe allergic reaction.

Before using Afrezza, your healthcare provider will take a medical history and do a physical exam and a breathing test (called spirometry) because Afrezza can cause a decline in lung function. Your healthcare provider will also want to test your breathing 6 months after starting Afrezza, and then each year after that.

Tell your doctor if you currently have lung cancer or have had it in the past.

You must test your blood sugar levels while using insulin such as Afrezza. Do not make any changes to your dose or type of insulin without talking to your healthcare provider. Any change of insulin should be made carefully and only under your healthcare provider's care.

The most common side effect of insulin, including Afrezza (insulin human) inhalation powder, is low blood sugar (hypoglycemia), which can be serious and life-threatening. Symptoms of low blood sugar include dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood change, hunger. Before you start using Afrezza, talk to your healthcare provider about low blood sugar and how to manage it.

Tell your doctor about all medicines you take, including prescription and over-the-counter medicines, vitamins or herbal supplements. Taking certain diabetes pills called TZDs (thiazolidinediones) with Afrezza can cause heart failure even if you have never had heart failure or heart problems before. If you already have heart failure or other heart problems, it may get worse while you take TZDs with Afrezza.

Before starting Afrezza, it is important to tell your doctor about all your medical conditions including if you have a history of lung problems, if you are pregnant or plan to become pregnant, or if you are breastfeeding or planning to breastfeed.

In addition to low blood sugar (hypoglycemia), other possible side effects associated with Afrezza® include cough, throat pain or irritation, headache, diarrhea, tiredness, and nausea. Please see full Prescribing Information for Afrezza, including Boxed WARNING and www.afrezza.com.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements that involve risks and uncertainties, including statements regarding MannKind's ability to promote Afrezza and the therapeutic potential of Afrezza. 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 the MannKind's current expectations. 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, the 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, 2016 and subsequent periodic reports on Form 10-Q and current reports on 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.

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