Insulet Corporation

May 2, 2013

# Insulet to Develop New Version of the OmniPod Insulin Pump for Use With Humulin R U-500 Concentrated Insulin for People With Type 2 Diabetes

BEDFORD, MA -- (Marketwired) -- 05/02/13 -- Insulet Corporation (NASDAQ: PODD), the leader in tubeless insulin pump technology with its OmniPod® Insulin Management System, today announced it has entered into an agreement with Eli Lilly and Company in which Insulet will develop a new version of the OmniPod insulin pump specifically designed to deliver Humulin® R U-500 insulin, (regular U-500 [Concentrated] insulin human injection, USP [rDNA origin]), a concentrated form of insulin used by people with highly insulin resistant type 2 diabetes. Insulet is partnering with Eli Lilly and Company on the clinical development program to evaluate the safety and efficacy of the combined delivery system.

As the incidence of severe insulin resistance continues to rise, more and more people with type 2 diabetes are requiring significantly higher doses of insulin in order to control their blood glucose. This new version of the OmniPod System would be the first insulin pump designed with specific feature modifications to deliver Humulin® R U-500 insulin. Given the rapid increases in rates of obesity and corresponding increases in daily insulin requirements, the new delivery system, if approved, would represents a significant and growing opportunity for people with highly insulin resistant type 2 diabetes to potentially better manage their disease with such a product.

"We are pleased to develop the first insulin pump specifically for Humulin® R U-500 insulin to bring the advantages of the OmniPod System to people with highly insulin resistant type 2 diabetes," said Duane DeSisto, President and Chief Executive Officer of Insulet. "The tubeless design of the OmniPod insulin pump provides freedom and ease of use for tens of thousands of people living with diabetes today."

***About the OmniPod Insulin Management System***
The OmniPod Insulin Management System is the world's first tubeless insulin pump. The OmniPod offers people living with insulin-requiring diabetes all the benefits of insulin pump therapy, with freedom and ease. The tubing-free OmniPod insulin pump has just two easy-to-use parts: the discreet, waterproof Pod, which automatically inserts and can be worn on many parts of the body to hold and deliver insulin; and the Personal Diabetes Manager (PDM), a hand-held device that wirelessly programs the Pod, calculates suggested doses and has a built-in blood glucose meter. To read inspiring stories of people with diabetes living their lives to the fullest with OmniPod, visit our customer blog, Suite D: http://suited.myomnipod.com. For more information on the OmniPod insulin pump, please visit: http://www.myomnipod.com.

***About Insulet Corporation***
Insulet Corporation (NASDAQ: PODD) is an innovative medical device company dedicated to making the lives of people with diabetes easier. Through its OmniPod Insulin Management System, Insulet seeks to expand the use of insulin pump therapy among people with insulin-dependent diabetes. The OmniPod is a revolutionary and easy-to-use tubeless insulin pump that features just two parts and fully-automated cannula insertion. Insulet's subsidiary, Neighborhood Diabetes, is a leading distributor for diabetes products and supplies, delivered through a high touch customer service model. Founded in 2000, Insulet Corporation is based in Bedford, Mass.

***About Humulin R U-500***

Humulin R U-500 is indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 1 and type 2 diabetes mellitus.

Humulin R U-500 is useful for the treatment of insulin-resistant patients with diabetes requiring daily doses of more than 200 units, since a large dose may be administered subcutaneously in a reasonable volume.

***Important Safety Information for Humulin R U-500***
***Contraindications***

- Humulin R U-500 is contraindicated during episodes of hypoglycemia and in patients hypersensitive to Humulin R U-500 or any of its excipients.

***Warnings***

- ***Starting or changing insulin therapy should be done cautiously and only under medical supervision.***
- ***Humulin R U-500 contains 500 units of insulin in each milliliter (5-times more concentrated than Humulin R U-100). For Humulin R U-500, extreme caution must be observed in the measurement of dosage because inadvertent overdose may result in serious adverse reaction or life-threatening hypoglycemia.***
- ***Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists:*** Thiazolidinediones (TZDs), which are PPAR-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin, including Humulin R U-500. Fluid retention may lead to or exacerbate heart failure. Observe patients for signs and symptoms of heart failure and consider discontinuation or dose reduction of the PPAR-gamma agonist.

***Precautions***

- ***Dosing Confusion/Dosing Errors:*** Medication errors associated with Humulin R U-500 have occurred and resulted in hyperglycemia, hypoglycemia, or death. The majority of errors occurred due to errors in dispensing, prescribing, or administration.
  - The Humulin R U-500 vial, which contains 20 mL, versus the Humulin R U-100 vial, which contains 10 mL, is marked with a band of diagonal brown stripes to distinguish it from the U-100 vial, which has no stripes. "U-500" is also highlighted in red on the label.
  - The prescribed dose of Humulin R U-500 should always be expressed in actual units of Humulin R U-500 along with corresponding markings on the syringe the patient is using (ie, a U-100 insulin syringe or volumetric [tuberculin or allergy] syringe).
  - A majority of administration errors occurred due to dosing confusion when the Humulin R U-500 dose was prescribed in units or volume corresponding to a U-100 insulin syringe or volumetric syringe markings, respectively, or the prescribed dose was administered without recognizing that the markings on the syringe used do not directly correspond to U-500 dose. Instructions for use should always be read and followed before use.
  - Instruct the patient to inform hospital or emergency department staff of the dose of Humulin R U-500 prescribed.
  - A conversion chart should always be used when administering Humulin R U-500 doses with U-100 insulin syringes or volumetric syringes.
- ***Hypoglycemia:*** Hypoglycemia is the most common adverse reaction of all insulin therapies, including Humulin R U-500. Hypoglycemia may occur suddenly. Severe hypoglycemia may lead to unconsciousness, convulsions, temporary or permanent impairment of brain function, or death. As with all insulin preparations, the time course of Humulin R U-500 action may vary in different individuals or at different times in the same individual and is dependent on dose, site of injection, blood supply, temperature, and physical activity.
  - Adjustment of dosage of any insulin may be necessary in patients with renal or hepatic impairment or if patients change their physical activity or their usual meal plan, or during times of illness, emotional disturbances, or other stresses. Concomitant oral antidiabetic treatment may need to be adjusted; however concomitant use is not recommended.
  - Any patient who requires Humulin R U-500 for control of diabetes should be under close observation until appropriate dosage is established. Insulin resistance may be transitory, and dosage requirements may change over time. Use caution in patients with hypoglycemia unawareness and in patients who may be predisposed to hypoglycemia. The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. These abilities are especially important in driving or operating other machinery.
  - Severe hypoglycemia may develop 18 to 24 hours after the original injection of Humulin R U-500.
- ***Hyperglycemia, Diabetic Ketoacidosis, and Hyperosmolar Non-Ketotic Syndrome:*** Hyperglycemia, diabetic ketoacidosis, or hyperosmolar coma may develop if the patient takes less Humulin R U-500 than needed to control blood glucose levels. Severe sustained hyperglycemia may result in hyperosmolar coma or death.
- ***Hypokalemia:*** Insulin use can lead to hypokalemia, that left untreated may cause respiratory paralysis, ventricular arrhythmia, and death. Use caution in patients who may be at risk for hypokalemia (eg, patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations).
- ***Hypersensitivity and Allergic Reactions:*** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including Humulin R U-500. Localized reactions and generalized myalgias have been reported.
- ***Renal or Hepatic Impairment:*** Frequent glucose monitoring and insulin dose reduction may be required.
- ***Drug Interactions:*** Some medications may alter insulin requirements and the risk for hypoglycemia and hyperglycemia. Some medications may mask the signs of hypoglycemia in some patients. Therefore, insulin dose adjustment and particularly close monitoring may be required.
- Pregnancy Category B: There are no adequate and well-controlled clinical studies of the use of Humulin R U-500 in pregnant or nursing women or during labor and delivery.
- ***Pediatric Use:*** There are no well-controlled studies of use of Humulin R U-500 in children.

***Adverse Reactions***

- ***Hypoglycemia:*** Hypoglycemia is one of the most frequent adverse events experienced by insulin users.

- Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, autonomic diabetic neuropathy, use of medications such as beta-adrenergic blockers, changing insulin preparations, or intensified control (3 or more insulin injections per day) of diabetes.
- Hypoglycemia when using Humulin R U-500 can be prolonged and severe.

- ***Additional adverse reactions include hypokalemia, lipodystrophy, local and systemic allergy, weight gain, and peripheral edema.***

***Dosage and Administration***

- The injection of Humulin R U-500 should be followed by a meal within approximately 30 minutes of administration.
- Humulin R U-500 should only be administered subcutaneously. Do not administer Humulin R U-500 intravenously or intramuscularly.
- ***Do not mix Humulin R U-500 with other insulins in the same syringe.***

***For more safety information, please click to access Patient Information and Full Prescribing Information.***

***Forward-Looking Statement***
This press release contains forward-looking statements within the meaning of the federal securities laws, including those related to the development of a new version of the OmniPod System and partnering with Eli Lilly and Company on a clinical development program. These forward-looking statements are based on Insulet's current expectations and beliefs concerning future developments and their potential effects on it. There can be no assurance that future developments affecting it will be those that it has anticipated. These forward-looking statements involve a number of risks, uncertainties (some of which are beyond its control) or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to: Insulet's ability to increase customer orders and manufacturing volumes; adverse changes in general economic conditions; impact of healthcare reform legislation; Insulet's inability to raise additional funds in the future on acceptable terms or at all; potential supply problems or price fluctuations with sole source or other third-party suppliers on which Insulet is dependent; failure by Insulet to retain key supplier and payor partners; international business risks; Insulet's inability to obtain adequate coverage or reimbursement from third-party payors for the OmniPod System and potential adverse changes in reimbursement rates or policies relating to the OmniPod System; failure to retain key partner payors and their members; potential adverse effects resulting from competition with competitors; technological innovations adversely affecting the Company's business; potential termination of Insulet's license to incorporate a blood glucose meter into the OmniPod System; Insulet's ability to protect its intellectual property and other proprietary rights; conflicts with the intellectual property of third parties, including claims that Insulet's current or future products infringe the proprietary rights of others; adverse regulatory or legal actions relating to the OmniPod System; failure of Insulet's contract manufacturers or component suppliers to comply with FDA's quality system regulations, the potential violation of federal or state laws prohibiting "kickbacks" or protecting patient health information, or any challenges to or investigations into Insulet's practices under these laws; product liability lawsuits that may be brought against Insulet; unfavorable results of clinical studies relating to the OmniPod System or the products of Insulet's competitors; potential future publication of articles or announcement of positions by physician associations or other organizations that are unfavorable to Insulet's products; the expansion, or attempted expansion, into foreign markets; the concentration of substantially all of Insulet's manufacturing capacity at a single location in China and substantially all of Insulet's inventory at a single location in Massachusetts; Insulet's ability to attract and retain key personnel; and other risks and uncertainties described in its Annual Report on Form 10-K for the year ended December 31, 2012, and in its other filings from time to time filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should any of its assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements. Insulet undertakes no obligation to publicly update or revise any forward-looking statements.

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