New Clinical Data Suggest Infusion Set with BD FlowSmart(TM) Technology May Improve Insulin Flow and Reduce Silent Occlusions

PR Newswire

Studies Presented at the American Diabetes Association's 75(th) Scientific Sessions Demonstrate Potential Benefits of Proprietary Side-Ported Catheter

BOSTON, June 6, 2015 /<u>PRNewswire</u>/ -- BD Medical, a segment of leading global medical technology company BD (Becton, Dickinson and Company) (NYSE: BDX), released research on infusion sets that represents a potential improvement in insulin pump therapy for people with diabetes. Three different posters will be presented at the American Diabetes Association's annual meeting with data on a new insulin infusion set with BD FlowSmart(TM) technology. Infusion sets have been described as "the Achilles heel" of insulin pump therapy. (i)

The insulin infusion set with BD FlowSmart technology was developed in collaboration with JDRF and The Leona M. and Harry B. Helmsley Charitable Trust to enhance the use of insulin pumps and improve the treatment of type 1 diabetes. This infusion set recently received both FDA clearance and Health Canada approval and is expected to be launched in 2016. An application has been submitted for CE marking.

"Silent occlusions have recently been recognized as a potential factor for unexplained hyperglycemia in some people using insulin pumps." said Laurence Hirsch, M.D., a study co-author and Worldwide Vice President of Medical Affairs, BD Medical-Diabetes Care. "They occur when there are interruptions to the flow of insulin from the pump to the body that do not trigger the pump occlusion alarm, leaving the pump user unaware of these lapses. Our research suggests that the BD infusion set can provide more consistent insulin delivery and may reduce the occurrence of silent occlusions, which is important news for insulin pump users."

1071-P: Continuous Subcutaneous Insulin Infusion Sets: Reduced Flow Interruptions with a Novel Catheter Set - Study Details

In this novel human study, researchers conducted a head-to-head comparison of the BD infusion set and the leading commercially available infusion set, in 60 healthy subjects, who received two insertions of each infusion set followed by infusions of insulin diluent. The results showed that pressure rise events or silent occlusions were reduced by 75 percent, p = 0.03, from 10.2 percent to 2.6 percent of infusions. A silent occlusion is defined as a continuous rise in pressure of at least 30 minutes. Decreasing such flow interruptions may benefit patients by providing more consistent insulin delivery.

1088-P: Performance Qualification of Novel Continuous Subcutaneous Insulin Infusion Set Using Medical Imaging - Study Details

This study used medical imaging techniques including MRI for the first time, to evaluate infusion catheter placement and fluid delivery patterns at various subcutaneous infusion sites. Studies conducted in both animals and people without diabetes assessed the performance of the BD side-ported catheter and other commercially-available catheters in their placement and delivery of insulin or insulin diluent. The images showed that the side port provides an additional flow pathway that may reduce occlusions and stabilize insulin flow.

1085-P: In Vivo Flow Evaluation and Correlation to Insulin Pharmacokinetics of Continuous Subcutaneous Insulin Infusion Sets - Study Details

This study examined the flow performance of the BD infusion set compared with three commercial sets and their recommended pumps. The research, performed in non-diabetic Yorkshire swine, used flow pressure monitoring along with insulin-level analyses. The BD infusion set showed reductions of 88-95 percent in mean percent time of flow interruption as compared to the commercial catheter sets.

To register for more information, please visit <u>www.bd.com/InfusionSet</u>

About BD

BD is a leading medical technology company that partners with customers and stakeholders to address many of the world's most pressing and evolving health needs. Our innovative solutions are focused on improving

medication management and patient safety; supporting infection prevention practices; equipping surgical and interventional procedures; improving drug delivery; aiding anesthesiology and respiratory care; advancing cellular research and applications; enhancing the diagnosis of infectious diseases and cancers; and supporting the management of diabetes. We are more than 45,000 associates in 50 countries who strive to fulfill our purpose of "Helping all people live healthy lives" by advancing the quality, accessibility, safety and affordability of healthcare around the world. In 2015, BD welcomed CareFusion and its products into the BD family of solutions. For more information on BD, please visit www.bd.com.

(i) Heinemann, L. and Krinelke, L. Insulin Infusion Set: The Achilles Heel of Continuous Subcutaneous Insulin Infusion. J Diabetes Sci Technol. 2012 Jul; 6(4): 954-964.

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