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**Valeritas Receives FDA 510(k) Clearance for the V-Go™
Disposable Insulin Delivery Device**

V-Go provides Type 2 diabetic patients a simple option for basal-bolus insulin therapy

Bridgewater, NJ, December 8, 2010 -- Valeritas, Inc., a medical technology company committed to the development and commercialization of innovative drug delivery solutions, announced today that the US Food and Drug Administration has cleared the company's V-Go Disposable Insulin Delivery Device for the continuous subcutaneous delivery of insulin in preset basal rates and with on-demand bolus dosing for adult patients requiring insulin. V-Go devices will be available in a preset basal rate to deliver 20, 30 or 40 Units of insulin in one 24-hour period (0.83 U/hr, 1.25U/hr or 1.67U/hr respectively) and on-demand bolus dosing in 2 Unit increments (up to 36 Units per one 24-hour time period).

“The V-Go Disposable Insulin Delivery Device is the first fully disposable, non-electronic basal-bolus device that is specifically designed with the Type 2 population in mind,” said Valeritas CEO Kristine Peterson. “We believe that the simple user features of the V-Go will allow more patients with diabetes to adhere to their insulin regimen, which ultimately may lead to better control.”

“The addition of the V-Go Disposable Insulin Delivery Device as an insulin delivery option for the Type 2 diabetic population is a great step forward in patient care. The more options these patients have the better,” said Nancy Bohannon, MD, an

endocrinologist from San Francisco, CA. “The V-Go provides a simple way to deliver basal-bolus insulin therapy, which I believe will increase patient compliance and improve glucose control in a very cost-effective manner compared to more traditional insulin delivery devices.”

Valeritas plans to commercialize the V-Go in the United States in 2011.

About the V-Go Disposable Insulin Delivery Device

The V-Go is the first simple, fully disposable device for the delivery of basal-bolus insulin therapy for adults with diabetes. The V-Go provides a continuous preset basal rate of insulin and allows for on-demand bolus dosing around mealtimes thereby providing an alternative to taking multiple daily insulin injections.

The V-Go is engineered to simplify basal-bolus insulin therapy for the millions of people suffering from Type 2 diabetes. The V-Go is small, lightweight, and worn under the patients’ clothing. It measures just 2.4 x 1.3 x 0.5 inches and weighs approximately 1 ounce when filled with insulin. Patients apply a new V-Go to the skin daily for one 24-hour period. The V-Go is not electronic, making it easy to operate and use.

About Valeritas, Inc.

Valeritas is a medical technology company committed to the development and commercialization of innovative drug delivery solutions that contribute to clinical and humanistic outcomes for patients, with an initial focus on the treatment of diabetes. The Valeritas medical technologies portfolio is headlined by the h-Patch™ technology. The V-Go Disposable Insulin Delivery Device, designed for the simple delivery of basal-bolus insulin therapy via a preset basal rate and on-demand bolus dosing around mealtimes, is the first use of the h-Patch™ technology.

In addition to the V-Go, the Valeritas delivery technology portfolio includes the h-Patch™ for the delivery of other compounds in addition to insulin, the Mini-Ject™ Pre-Filled Needle-Free Delivery System, and the Micro-Trans™ Microneedle Delivery

System. These technologies, when combined with certain compounds, are designed to enhance the delivery of a variety of injectable drugs resulting in improved patient acceptance and outcomes.

Headquartered in Bridgewater, NJ, Valeritas operates its R&D and manufacturing in a state-of-the-art facility in Shrewsbury, MA. Valeritas' primary investors include MPM Capital, Pitango Venture Capital, Abingworth, US Venture Partners, ONSET Ventures, Advanced Technology Ventures, HLM Venture Partners, CHL Medical Partners, Kaiser Permanente Ventures, and Agate Medical Investments.

Information on Valeritas and the V-Go™ Disposable Insulin Delivery Device can be found at www.valeritas.com.

About Diabetes

Diabetes is a chronic and progressive disease in which the body fails to produce or properly utilize insulin, a hormone that regulates blood sugar (glucose) levels.¹ High blood glucose levels can lead to serious complications, including heart disease, stroke, high blood pressure, blindness, kidney disease, amputation, and even premature death.²

Approximately 23.6 million US children and adults have diabetes, including nearly 6 million who are undiagnosed.² Diabetes is classified as Type 1 or Type 2. The Type 2 form of the disease is most common, affecting approximately 95% of adults with diabetes.¹ In Type 2 diabetes, either the body does not produce enough insulin or the body's cells do not use insulin properly.¹ In Type 1 diabetes, the body stops producing insulin altogether.^{1,3}

To control blood glucose levels, approximately 4.5 million people in the US with Type 2 diabetes take insulin⁴, which is usually administered by injection. About 3 million of these insulin users have not achieved target glucose levels currently recommended by the American Diabetes Association.^{4,5} In addition, many people with Type 2 diabetes could benefit from insulin therapy, but refuse to start on therapy or skip taking insulin for a

variety of reasons, including interference with daily activities, injection pain, and embarrassment about injecting medication around family and friends or in public.^{6,7} In one study, approximately 80% of Type 2 diabetes patients only required a single daily basal rate of insulin.⁸ Using continuous subcutaneous insulin infusion therapy for Type 2 diabetes mellitus patients may lead to improved glycemic control.

References:

1. Centers for Disease Control and Prevention. National diabetes fact sheet: general information and national estimates on diabetes in the United States, 2007. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention; 2008.
2. American Diabetes Association. Diabetes statistics. <http://www.diabetes.org/diabetes-basics/diabetes-statistics/>. Accessed December 6, 2010.
3. American Diabetes Association. Diabetes basics: Type 1. <http://www.diabetes.org/diabetes-basics/Type-1/>. Accessed December 6, 2010.
4. Roper Diabetes Patient Market Study. GfK Market Measure, 2008.
5. Hoerger TJ, Segal JE, Gregg EW, Saaddine JB. Is glycemic control improving in U.S. Adults? *Diabetes Care*. 2008;31(1):81-86.
6. Marcus MB. 57% of diabetics occasionally skip insulin shots on purpose. *USA Today*. January 25, 2010. http://www.usatoday.com/news/health/2010-01-26-insulin26_ST_N.htm. Accessed December 6, 2010.
7. Petrak F, Stridde E, Leverkus F, Crispin AA, Forst T, Pfützner A. Development and validation of a new measure to evaluate psychological resistance to insulin treatment. *Diabetes Care*, 2007;30(9):2199-2204.
8. Frias JP, Edelman SV, Bode BW, et al. Insulin pump therapy using a simple dosing regimen safely improved glycemic control and patient reported outcomes in patients with Type 2 diabetes suboptimally controlled with multiple daily injections. In: Proceedings from the AACE 19th Annual Meeting and Clinical Congress; April 21–25, 2010; Boston, MA. Abstract 212.