

Valeritas Receives European CE Mark Approval for the V-Go™ Disposable Insulin Delivery Device

BRIDGEWATER, N.J., July 25, 2011 /PRNewswire/ -- Valeritas, Inc., a medical technology company focused on the development and commercialization of innovative drug delivery solutions, announced today it received CE Mark approval for its V-Go™ Disposable Insulin Delivery Device as well as ISO 13485: 2003 Quality Management System Certification. The V-Go is designed to provide simple basal-bolus therapy for adults who require insulin therapy.

"These are important corporate milestones for Valeritas as we evaluate the commercialization of the V-Go outside of the United States," said Valeritas CEO Kristine Peterson. "The CE Mark, coupled with our FDA 510(k) clearances in December 2010 and February 2011, affords us the opportunity to provide an innovative therapeutic option to the millions of adults who require insulin to treat their diabetes."

More than 55 million adults in Europe have diabetes(1) – and in countries where the CE Mark applies there are approximately 37.5 million adults who suffer from diabetes(2). Valeritas estimates over 5 million of these patients use insulin today as part of their therapeutic regimen.

"The V-Go is a patient-friendly, basal-bolus insulin delivery device that could substantially improve compliance which would help patients better manage their diabetes," said Poul Strange, MD, PhD, Valeritas Medical Consultant and Founder of Integrated Medical Development.

About the V-Go Disposable Insulin Delivery Device

The V-Go is the first simple, fully disposable device designed and approved 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.

In December 2010, Valeritas received FDA 510(k) clearance for the V-Go's use with Humalog® and in February 2011 received FDA 510(k) clearance for use with NovoLog®.

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.

The V-Go is filled with insulin using a very simple disposable point-of-care filling accessory – the V-Go™ EZ Fill (which will be included with each monthly supply of V-Go devices). A separate prescription for insulin is required for use with the V-Go. Humalog® and NovoLog® have both been tested by Valeritas, Inc. and found safe for use with the V-Go Disposable Insulin Delivery Device.

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, ATV Capital, 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 and www.go-vgo.com.

Humalog is a registered trademark of Eli Lilly and Company.

NovoLog is a registered trademark of Novo Nordisk A/S.

References:

1. International Diabetes Federation. Diabetes Atlas <http://www.idf.org/diabetesatlas/europe>. Accessed July 22, 2011.
2. International Diabetes Federation. Diabetes Atlas – Maps. <http://archive.diabetesatlas.org/map>. Accessed July 22, 2011.

CONTACT: Tara Charvat, Valeritas, Inc., +1-908-927-9920 x20110, TCharvat@valeritas.com