Valeritas ENABLE Study Demonstrates Significant Clinical Benefits of V-Go in Patients with Type 2 Diabetes Who Switched from Insulin Pens and Syringes

- Data Presented at Annual ADA Meeting Reports Patients with Type 2 Diabetes who Switched to V-Go® had Significant Improvement in Blood Glucose and Used Less Insulin -

BRIDGEWATER, New Jersey, June 25, 2018 --- Valeritas Holdings, Inc. (NASDAQ: VLRX), a medical technology company and maker of V-Go® Wearable Insulin Delivery device—a simple, all-in-one, wearable insulin delivery option for patients with diabetes—announced today positive results from the EffectiveNess of V-Go WeArable Insulin Delivery for Basal-BoLus ThErapy (ENABLE) Study.

Three poster presentations at the American Diabetes Association Meeting in Orlando, Florida, reported that patients who switched from insulin pens and syringes to V-Go significantly improved blood glucose while lowering insulin dose.

Valeritas CEO, John Timberlake, commented, “The largest study of V-Go patients to date has demonstrated that regardless of baseline insulin dose or duration of diabetes, patients who switched to V-Go significantly lowered their blood glucose. We believe that is significant for diabetes patients, their medical professionals, payors, and Valeritas.”

Mr. Timberlake continued, “We recently reported our third consecutive quarter of record revenue which is a direct result of V-Go gaining momentum among patients with type 2 diabetes. V-Go is discreet, simple-to-use, cost-effective, clinically proven, and the only disposable, daily insulin delivery option.”

Poster 988 - EffectiveNess of V-Go WeArable Insulin Delivery for Basal-BoLus ThErapy (ENABLE) Study: A Multicenter Retrospective Real World Evaluation in Type 2 Diabetes.

The first ENABLE Study poster evaluated the clinical benefits in patients with type 2 diabetes who switched from using insulin pens and syringes to deliver their insulin regimen with V-Go for insulin delivery. The 283 patient, retrospective study demonstrated clinically and statistically significant reductions in A1C by over 1% (a measure of blood glucose control), and insulin total daily dose (TDD) at three and seven months. The percent of patients at high risk (A1C > 9%) was reduced by nearly 50% after switching to V-Go. In addition, over 50% of all patients in the study achieved an A1C less than 8%.

“We categorize patients with an A1C above 9.0% as high risk since they are more likely to have long-term complications that impact health care costs. The significant reduction in A1C and the achievement in A1C goals after switching to V-Go in the ENABLE study has important implications for treating diabetes. By improving glycemic control, our hope is to reduce rates of complications as well as decrease health care cost, which is a priority for all healthcare systems.” said lead author and endocrinologist Ripu Hundal, M.D., of First State Endocrinology in Newark, Delaware.
After three and seven months of V-Go use, significant reductions were observed in both A1C (-1.01 and -1.04; p<0.0001) and TDD (-17 U/day and -14 U/day; p<0.0001).

**Poster 989 - Achievement of Glycemic Targets when Switching from Basal-Bolus Therapy to V-Go for Insulin Delivery in Type 2 Diabetes.**

The second analysis from the ENABLE study confirmed V-Go provided a clinical benefit in a patient population poorly controlled on conventional basal-bolus therapy delivered by multiple daily injections (MDI) using insulin pens and syringes.

The analysis in 186 patients with type 2 diabetes demonstrated lowering of A1C by -1.0 at three months which was sustained at seven months and statistically significant with a P<0.0001. Insulin TDD was reduced by 30% (84 U/day to 59 U/day) with V-Go use. To determine if TDD was a factor in the change in A1C, patients were separated into three approximately equal groups based on baseline TDD (< 60 U/day [mean of 46 U/day], 60 to 90 U/day [mean of 72 U/day], or > 90 U/day [mean of 134 U/day]). Results demonstrated statistically significant A1C reductions across all TDD groups of -1.0, -0.8, -1.2, respectively, each with a P<0.001.

**Poster 990 - Clinical Outcomes with V-Go in Type 2 Diabetes based on Duration of Diabetes.**

The third ENABLE study poster evaluated the impact of duration of diabetes on change in A1C and insulin TDD when switching patients with type 2 diabetes from insulin delivery via insulin pen or syringe to V-Go. Patients with known duration of diabetes were stratified into five groups based on duration of diabetes (years). Clinically and statistically significant reductions in A1C from baseline at both three and seven-month intervals were observed in all five duration of diabetes strata. All strata also benefited from reductions in TDD with the exception of the duration stratum with the lowest baseline TDD (15 to 20 years), which maintained similar dosing on V-Go compared to baseline.

“Findings from the ENABLE Study demonstrated that no matter how long a patient had been diagnosed with diabetes, switching to V-Go from insulin delivery via insulin pen or syringe resulted in significantly lower A1C levels,” said lead author, Jane Cases, M.D., of Marietta, Ohio. “We believe this positive data demonstrates that diabetes duration should not be a factor when determining which patient can benefit from using V-Go.”

**About Valeritas Holdings, Inc.**

Valeritas is a commercial-stage medical technology company focused on improving health and simplifying life for people with diabetes by developing and commercializing innovative technologies. Valeritas’ flagship product, **V-Go® Wearable Insulin Delivery device**, is a simple, affordable, all-in-one basal-bolus insulin delivery option for patients with diabetes that is worn like a patch and can eliminate the need for taking multiple daily shots. V-Go administers a continuous preset basal rate of insulin over 24 hours, and it provides discreet on-demand bolus dosing at mealtimes. It is the only basal-bolus insulin delivery device on the market today specifically designed keeping in mind the needs of type 2 diabetes patients. Headquartered in Bridgewater, New Jersey, Valeritas operates its R&D functions in Marlborough, Massachusetts.
More information is available at www.valeritas.com and our Twitter feed @Valeritas_US, www.twitter.com/Valeritas_US.

Forward-Looking Statements

This press release may contain forward-looking statements. Statements in this press release that are not purely historical are forward-looking statements. Such forward-looking statements include, among other things, references to Valeritas technologies, business and product development plans and market information. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, the ability to raise the additional funding needed to continue to pursue Valeritas’ business and product development plans, the inherent uncertainties associated with developing new products or technologies, the ability to commercialize the V-Go® Wearable Insulin Delivery device with limited resources, competition in the industry in which Valeritas operates and overall market conditions. Any forward-looking statements are made as of the date of this press release, and Valeritas assumes no obligation to update the forward-looking statements or to update the reasons why actual results could differ from those projected in the forward-looking statements, except as required by law. Investors should consult all of the information set forth herein and should also refer to the risk factor disclosure set forth in the reports and other documents Valeritas files with the SEC available at www.sec.gov.

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