Valeritas Presents Positive h-Patch™ Apomorphine Study Data at Global Experts Meeting on Frontiers in Alzheimer’s Disease & Dementia

BRIDGEWATER, New Jersey, October 15, 2019 --- Valeritas Holdings, Inc. (NASDAQ: VLRX), a medical technology company and maker of the V-Go® Wearable Insulin Delivery device, which uses its proprietary h-Patch™ technology, announced positive data from its preclinical pharmacokinetic (PK) study of apomorphine (APO) subcutaneous infusion was presented today at Global Experts Meeting on Frontiers in Alzheimer's Disease & Dementia (Dementia 2019) in Rome, Italy.

In the poster presentation titled “Preclinical Pilot Study Result of 24-Hour Apomorphine Subcutaneous Infusion Delivered via the h-Patch™ Wearable Device,” the data demonstrated rapid absorption and distribution of 400ul of a 25mg/ml APO solution with the h-Patch™ technology. APO was detected in plasma within two hours of the start of infusion, and still detectable 24 hours after completion of h-Patch™ infusion, or 48 hours in total.

“The study presented demonstrates that a non-peptide therapeutic like apomorphine can be delivered via our simple all-in-one, fully disposable, h-Patch™ subcutaneous drug delivery device,” said John Timberlake, President and Chief Executive Officer of Valeritas.

Valeritas’ h-Patch™ is a drug delivery technology that can facilitate the simple and effective subcutaneous delivery of injectable medicines to patients across a broad range of therapeutic areas. The company’s V-Go is the first FDA-approved product that utilizes the h-Patch™ technology. To date, more than 20 million V-Go insulin delivery devices have been sold in the United States.

Treatment of advanced Parkinson’s disease (PD) remains challenging, with fluctuations in motor status often resulting in patients becoming severely handicapped. The magnitude and pattern of the motor response to a single dose of subcutaneously administered Apo are qualitatively comparable to that of oral levodopa; however, side effects of oral dosing (nausea, vomiting, etc.) can be problematic.

Close to a dozen clinical studies have shown subcutaneous Apo infusions are successful in aborting “off” periods, reducing dyskinesias, and improving PD motor scores with the added benefit of a substantial levodopa-sparing effect. However, bulky infusion pumps requiring delivery of relatively large volumes of therapeutics remain a barrier to the development of therapeutic products that are patient and caregiver friendly.
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 adult patients requiring insulin 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, 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; Valeritas’ expected cash burn rate and its ability to continue to increase new and total prescription growth; the expected benefits of the debt exchange on Valeritas’ cash runway and its anticipated operating costs following the debt exchange (the $2 million minimum debt covenant remains in place following the debt exchange, which will continue to limit Valeritas’ ability to finance its operations); the effects of both the new issuance of Series B Convertible Preferred Stock and the May 2019 reverse stock split on the trading price of Valeritas’ common stock, in both the short and long-term; the ability to continue to commercialize the V-Go® Wearable Insulin Delivery device with limited resources, competition in the industry in which Valeritas operates and overall market conditions; the inherent uncertainties associated with developing new products or technologies; the potential commercial use of the h-Patch™ technology for subcutaneous delivery of Apo or CBD is dependent on Valeritas’ ability to identify one or more potential collaboration partners and enter into mutually agreeable collaboration agreements (neither the delivery of Apo or CBD by h-Patch™ is currently cleared for use by the FDA); our statements that (i) subcutaneous Apo infusions appears to offer qualitatively comparable benefits to that of oral levodopa and (ii) based on initial studies, subcutaneous infusion of CBD appears to offer several distinct advantages over oral dosing of CBD, and other potential benefits of the h-Patch™ technology to deliver Apo or CBD is based on third-party clinical studies not conducted by Valeritas; however, additional studies or research may be needed by our potential partners to demonstrate to the U.S. Food and Drug Administration (“FDA”) that delivery of Apo or CBD via the h-Patch™ technology will offer consistent results to the initial Valeritas study; and the FDA or other regulatory agencies may require Valeritas’ collaboration partners to demonstrate the safety or
effectiveness of subcutaneous infusion of Apo or CBD through the h-Patch™ technology before either of those products can be commercialized, which can be a lengthy, and uncertain process, and the FDA may delay or require additional information to provide clearance for use with our RHI or our V-Go SIM product. Statements or claims made by third parties regarding the efficacy or functionality of V-Go as compared to other products are statements made by such individual and should not be taken as evidence of clinical trial results supporting such statements or claims. 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](http://www.sec.gov).

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