



NEWS RELEASE

Viridian Therapeutics Announces U.S. FDA Approval and Launch of Lumvoa™ (veligrotug-vvze) for the Treatment of Thyroid Eye Disease

2026-06-26

- First approved treatment for thyroid eye disease (TED) with labeling that includes data for both active and chronic TED -
- In two pivotal phase 3 clinical trials, Lumvoa treatment showed rapid, consistent, and durable reductions of the key signs and symptoms of both active and chronic TED -
- Lumvoa is the first approved product for TED to show a statistically significant effect in both diplopia response and complete resolution of diplopia in active and chronic disease -
- Viridian plans to launch Lumvoa immediately, a pivotal milestone as the company's first commercial product in TED with subcutaneous elegrobarb on track for a biologics license application (BLA) submission in Q1 2027 -
- Viridian will host a conference call and webcast Monday, June 29 at 8:00 a.m. ET -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (Nasdaq: VRDN), a biotechnology company focused on discovering, developing, and commercializing potentially best-in-class medicines for autoimmune and rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has approved Lumvoa™ (veligrotug-vvze) for the treatment of thyroid eye disease (TED). TED is a rare, debilitating autoimmune disease characterized by inflammation and tissue remodeling around and behind the eyes that can lead to proptosis, diplopia, pain, and vision impairment.

“With the approval of Lumvoa, we take a significant step forward in providing a meaningful treatment option for

people living with thyroid eye disease,” said Steve Mahoney, President and Chief Executive Officer of Viridian. “Lumvoa was designed with patient needs at the forefront and is Viridian’s first FDA-approved medicine and our first commercial product. This marks an important milestone for us and reflects years of focused execution by the Viridian cross-functional teams. Our commercial and medical affairs teams have been preparing for this moment for a long time, and in particular since receiving Breakthrough Therapy Designation last year. We are ready to support patients and physicians from day one.”

“The Lumvoa development program was a robust evaluation of the drug across the full spectrum of TED, including both active and chronic disease, showing significant improvements in outcomes that matter to patients and clinicians,” said Michael Yen, M.D., Professor of Oculoplastic Surgery and Ophthalmology at Baylor College of Medicine and an investigator in the THRIVE program. “It’s encouraging to see a new treatment for the full spectrum of the disease with data showing rapid onset of proptosis reduction as well as improvements in diplopia. This is an exciting new option for physicians to offer their TED patients.”

“The TED community is pleased to see this important advancement in the treatment of TED. TED can be physically painful and emotionally exhausting, and patients experience the disease as highly disruptive to their daily lives,” said Christine Gustafson, Founder, Chief Executive Officer, and Executive Director, TED Community Organization. “Having a new treatment available could be very important for the many patients who are seeking help for thyroid eye disease.”

Immediate Launch of Lumvoa Supported by Comprehensive Patient Support Program

Viridian plans to launch Lumvoa immediately, and physicians can prescribe Lumvoa tomorrow. Viridian has worked closely with payers, healthcare providers, and patient advocates to support broad access to Lumvoa. As part of this commitment, Viridian has created ViridianCares™, a comprehensive patient support program that provides dedicated patient access liaisons, insurance coverage support and benefit verification, and financial assistance programs for eligible patients, to help patients and caregivers navigate the treatment journey and receive therapy as prescribed. For more information on ViridianCares, call 866-VCARES1 (866-822-7371).

Approval Supported by Pivotal THRIVE and THRIVE-2 Clinical Trials

Lumvoa was approved by the FDA under Priority Review and supported by the THRIVE (active TED) and THRIVE-2 (chronic TED) pivotal phase 3 clinical trials. Lumvoa is a full antagonist of IGF-1R and the first approved treatment for TED with labeling that includes data for both active and chronic TED. Both the THRIVE and THRIVE-2 clinical trials met their respective primary and all secondary endpoints, consistently demonstrating statistically significant and clinically meaningful improvements at week 15 across all of the key signs and symptoms of TED.

Across both clinical trials, patients received a 12-week course of Lumvoa designed to reduce the burden of

treatment. Lumvoa demonstrated a rapid onset of clinical benefit, with reductions in proptosis observed as early as three weeks. Lumvoa is the first approved product for TED to show a statistically significant effect in both diplopia response and complete resolution in active and chronic TED. Lumvoa was granted Breakthrough Therapy Designation and Priority Review by the FDA.

Conference Call and Webcast Information

Viridian will host a conference call and webcast Monday, June 29 at 8:00 a.m. ET to discuss the FDA approval of Lumvoa. The dial-in number for the conference call is (800) 715-9871 for domestic participants and +1 (646) 307-1963 for international participants. The conference ID is 2419136.

A live webcast of the conference call can be accessed through the “Events” page in the Investors section of the Viridian Therapeutics website. Following the live webcast, an archived version of the call will also be available on the website.

Lumvoa U.S. Indication

Lumvoa is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.

Important Safety Information

Infusion Reactions

Lumvoa may cause infusion reactions. Infusion reactions have been reported in approximately 9% of patients treated with Lumvoa. Signs and symptoms of infusion-related reactions include transient increases in blood pressure, fever, chills, headache, and fatigue. Infusion reactions may occur during or soon after an infusion. Reported infusion reactions are usually mild or moderate in severity and can usually be successfully managed with corticosteroids, antihistamines, and antipyretics. In patients who experience an infusion reaction, consideration should be given to standard premedication and/or administering infusions at a slower infusion rate.

Inflammatory Bowel Disease

Lumvoa may cause an exacerbation of inflammatory bowel disease (IBD). IBD has been reported in some patients receiving insulin-like growth factor-1 receptor inhibitors without a prior diagnosis of IBD. Monitor patients for signs and symptoms of IBD, including patients without a history of IBD. If IBD is suspected, discontinue use of Lumvoa.

Hyperglycemia

Hyperglycemia or increased blood glucose may occur in patients treated with Lumvoa. In clinical trials, 12% of patients, of whom one-half had preexisting diabetes or impaired glucose tolerance, experienced hyperglycemia. Hyperglycemic events should be controlled with medications for glycemic control, if necessary. Assess patients for elevated blood glucose and symptoms of hyperglycemia prior to infusion and continue to monitor while on

treatment with Lumvoa. Ensure patients with hyperglycemia or preexisting diabetes are under appropriate glycemic control before and while receiving Lumvoa. Continue monitoring after treatment for patients who experience hyperglycemia while on Lumvoa.

Hearing Impairment Including Hearing Loss

Lumvoa may cause severe hearing impairment including hearing loss, which in some cases may be permanent. Assess patients' hearing before, during, and after treatment with Lumvoa and consider the benefit-risk of treatment with patients.

Most Common Adverse Events

Most common adverse reactions (incidence of 5% or more) are muscle spasms, headache, hearing impairment, hyperglycemia, fatigue, diarrhea, ear discomfort, infusion-related reaction, nausea, nasopharyngitis, blood creatine phosphokinase increased, dry skin, and hypertension.

Females of Reproductive Potential

Appropriate forms of contraception should be implemented prior to initiation, during treatment, and for 6 months following the last dose of Lumvoa.

Lumvoa (500 mg) is an injection for infusion.

Please see the full Prescribing Information for Lumvoa at: <https://www.viridiantherapeutics.com/lumvoa-prescribing-information/>

About Lumvoa™ (veligrotug-vvze)

Lumvoa™ (veligrotug-vvze) is approved by the U.S. Food and Drug Administration for the treatment of thyroid eye disease (TED). Lumvoa is a full antagonist of IGF-1R and the first approved treatment for TED with labeling that includes data for both active and chronic TED data based on positive data from the two largest pivotal phase 3 clinical trials completed in TED to date. Lumvoa is administered over 12 weeks as five intravenous infusions, each given every three weeks.

About Viridian Therapeutics

Viridian Therapeutics is a biotechnology company dedicated to developing better medicines for patients with autoimmune and rare diseases. Utilizing our expertise in antibody discovery and protein engineering, we aim to build on proven science to develop innovative medicines that address unmet needs and improve patient outcomes.

With an immediate focus in thyroid eye disease (TED), we developed Lumvoa, a full IGF-1R antagonist approved by the U.S. FDA for the treatment of thyroid eye disease. We are also advancing elegrobar, a late-stage investigational

subcutaneous therapy designed to further address unmet needs in TED and improve patient convenience. Beyond TED, we are advancing a pipeline of potential best-in-class medicines to address multiple serious autoimmune diseases.

Viridian is headquartered in Waltham, Massachusetts. For more information, please visit

www.viridiantherapeutics.com. Follow Viridian on **LinkedIn** and **X**.

Forward Looking Statements

This press release contains forward-looking statements. These statements may be identified by the use of words such as, but not limited to, “anticipate,” “believe,” “become,” “continue,” “could,” “design,” “estimate,” “expect,” “intend,” “may,” “might,” “on track,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or other similar terms or expressions that concern our expectations, plans and intentions. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations, and assumptions. Forward-looking statements include, without limitation: that the Company intends to launch Lumvoa immediately and that physicians may prescribe Lumvoa tomorrow; that the Company’s commercial and medical affairs teams are ready to support patients and physicians; that Lumvoa will be a meaningful treatment option for people living with thyroid eye disease; Viridian’s product candidates potentially being best-in-class; whether elegrobarb will serve an unmet need; elegrobarb’s potential to improve patient convenience. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. Such forward-looking statements are subject to a number of material risks and uncertainties including but not limited to: potential utility, efficacy, potency, safety, clinical benefits, clinical response, and convenience of Viridian’s product and product candidates; that results or data from completed or ongoing clinical trials may not be representative of the results of ongoing or future clinical trials; that preliminary data may not be representative of final data; expectations and changes regarding the timing for regulatory filings; regulatory interactions; uncertainty and potential delays related to clinical drug development; the timing of and our ability to obtain and maintain regulatory approvals for our therapeutic candidates; competition from other therapies or products; estimates of market size; our future operating results and financial performance; Viridian’s intellectual property position; that our product and product candidates may not be commercially successful, if approved; and other risks described from time to time in the “Risk Factors” section of our filings with the Securities and Exchange Commission (SEC), including those described in our most recent Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as applicable, and supplemented from time to time by our Current Reports on Form 8-K. Any forward-looking statement speaks only as of the date on which it was made. Neither the company, nor its affiliates, advisors, or representatives, undertake any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing the company’s views as of any date

subsequent to the date hereof.

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Source: Viridian Therapeutics, Inc.