NEWS RELEASE

Viridian Therapeutics Announces BLA Acceptance and Priority Review for Veligrotug for the Treatment of Thyroid Eye Disease

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- PDUFA target action date of June 30, 2026 -

- Priority Review designation is granted to applications for drugs that, if approved, would be a significant improvement in the safety or effectiveness of treating a serious condition -

- Veligrotug now has both Priority Review and Breakthrough Therapy Designations, each following requests which included data on veligrotug's (i) consistent and robust improvement and resolution of diplopia in chronic TED, and (ii) rapid onset of proptosis response -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (Nasdaq: VRDN), a biotechnology company focused on discovering, developing, and commercializing potentially best-in-class medicines for serious and rare diseases, today announced that the U.S. Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for veligrotug for the treatment of thyroid eye disease (TED). The application has been granted Priority Review, with a Prescription Drug User Fee Act (PDUFA) target action date of June 30, 2026.

Priority Review shortens the BLA target review timeline to six months from ten months after the FDA accepts the BLA. This designation is granted to applications for drugs that, if approved, would be a significant improvement in the safety or effectiveness of treating a serious condition. Priority Review is the second FDA designation granted for veligrotug in 2025. In May 2025, the agency granted veligrotug Breakthrough Therapy Designation. Each of these requests included phase 3 clinical trial data on veligrotug's (i) consistent and robust improvement and resolution of diplopia in chronic TED, and (ii) rapid onset of proptosis response.

“We are thrilled that the FDA granted Priority Review for veligrotug, marking another significant milestone for Viridian and the TED community,” said Steve Mahoney, Viridian’s President and CEO. “This designation is a recognition that, if approved, veligrotug would be a significant improvement in the safety or effectiveness of treating a serious condition. This achievement also reflects the Viridian team’s excellent execution and dedication. We very much appreciate all of the support we’ve received from patients, investigators, and our clinical partners. We look forward to working closely with the FDA as we advance toward our goal of delivering a potentially transformative therapy to people living with thyroid eye disease and establishing Viridian as a leading commercial company in TED.”

The veligrotug BLA is supported by positive data from two of the largest phase 3 clinical trials conducted in TED to date. In THRIVE and THRIVE-2, conducted in active and chronic TED patients, respectively, veligrotug met the primary and all secondary endpoints of each study as well as demonstrated a rapid onset of clinical benefit. For the first time in a phase 3 clinical trial in chronic TED, veligrotug demonstrated statistically significant diplopia response and diplopia resolution. Veligrotug, if approved, would provide patients with an attractive treatment option with a five-infusion treatment course enabling patients to complete treatment in 12 weeks. Veligrotug was generally well-tolerated in its phase 3 clinical trials.

Preparations are well underway for veligrotug’s anticipated commercial launch. The company also plans to submit a Marketing Authorization Application to the European Medicines Agency in the first quarter of 2026.

About Veligrotug

Veligrotug is an intravenously delivered, anti-insulin-like growth factor-1 receptor (IGF-1R) antibody in phase 3 development for thyroid eye disease, with the potential to be the IV treatment-of-choice for active and chronic TED patients. Based on clinical data to date, veligrotug has demonstrated robust clinical activity and was generally well-tolerated.

Both pivotal phase 3 clinical trials, THRIVE and THRIVE-2, reported positive topline data, meeting the primary and all secondary endpoints of each study. In these studies, veligrotug demonstrated a rapid onset of clinical benefit and statistically significant, clinically meaningful effects on multiple diplopia endpoints in both clinical trials, including the first demonstration of diplopia response and resolution in a global chronic TED phase 3 study. Following these results, veligrotug was granted Breakthrough Therapy Designation in May 2025. The FDA also granted the veligrotug BLA a Priority Review with a PDUFA target action date of June 30, 2026. Both Breakthrough Therapy and Priority Review Designations were supported by phase 3 clinical trial data on veligrotug’s consistent and robust improvement and resolution of diplopia in chronic TED, and rapid onset of proptosis response.

About Viridian Therapeutics

Viridian is a biopharmaceutical company focused on discovering, developing, and commercializing potential best-in-class medicines for patients with serious and rare diseases. Viridian's expertise in antibody discovery and protein engineering enables the development of differentiated therapeutic candidates for previously validated drug targets in commercially established disease areas.

Viridian is advancing multiple candidates in the clinic for the treatment of patients with thyroid eye disease (TED). The company conducted a pivotal program for veligrotug (VRDN-001), including two global phase 3 clinical trials (THRIVE and THRIVE-2), to evaluate its efficacy and safety in patients with active and chronic TED. Both THRIVE and THRIVE-2 reported positive topline data, meeting the primary and all secondary endpoints of each study. Viridian is also advancing VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED, including two ongoing global phase 3 pivotal clinical trials, REVEAL-1 and REVEAL-2, to evaluate the efficacy and safety of VRDN-003 in patients with active and chronic TED.

In addition to its TED portfolio, Viridian is advancing a novel portfolio of neonatal Fc receptor (FcRn) inhibitors, including VRDN-006 and VRDN-008, which have the potential to be developed in multiple autoimmune diseases.

Viridian is based 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 within the meaning of the Private Securities Litigation Reform Act of 1995. 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, statements regarding: preclinical development, clinical development, and anticipated commercialization of Viridian's product candidates veligrotug, VRDN-003, VRDN-006, and VRDN-008; Viridian's expectations regarding regulatory interactions and anticipated timing of regulatory submissions, including a Marketing Authorization Application to the European Medicines Agency, and review timelines; veligrotug's potential to be an attractive treatment option for patients and the IV treatment-of-choice for active and chronic TED; veligrotug's potential to be a transformative therapy for people living with TED; Viridian's product candidates potentially being best-in-class; Viridian's expectations regarding the potential commercialization of veligrotug, if approved and potential to become a leading commercial company in

TED.

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 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; the timing, progress and plans for our ongoing or future research, preclinical, and clinical development programs; changes to trial protocols for ongoing or new clinical trials; expectations and changes regarding the timing for regulatory filings; regulatory interactions; expectations and changes regarding the timing for enrollment and data; uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in our clinical programs; the timing of and our ability to obtain and maintain regulatory approvals for our therapeutic candidates; manufacturing risks; competition from other therapies or products; estimates of market size; other matters that could affect the sufficiency of existing cash, cash equivalents, and short-term investments to fund operations; our financial position and projected cash runway; our future operating results and financial performance; Viridian's intellectual property position; the timing of preclinical and clinical trial activities and reporting results from same; that our 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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