



NEWS RELEASE

# Viridian Therapeutics Announces Positive Long-Term Durability Data from the Veligrotug Phase 3 THRIVE Clinical Trial in Patients with Active Thyroid Eye Disease (TED)

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- 70% of patients treated with veligrotug in THRIVE who were proptosis responders at week 15 maintained their response at week 52 -

- Veligrotug recently received Breakthrough Therapy Designation (BTD), supporting eligibility for Priority Review; the BTD request was based on veligrotug's (i) consistent and robust improvement and resolution of diplopia in chronic TED, and (ii) rapid onset of proptosis response -

- Biologics License Application (BLA) submission for veligrotug is on track for second half 2025 -

- Actively preparing organization for planned U.S. commercial launch in 2026 -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (Nasdaq: VRDN), a biopharmaceutical company focused on discovering, developing, and commercializing potential best-in-class medicines for serious and rare diseases, today announced positive long-term durability data from the THRIVE phase 3 clinical trial of veligrotug ("veli"), an intravenously delivered anti-insulin-like growth factor-1 receptor (IGF-1R) antibody, in patients with active thyroid eye disease (TED). TED is an autoimmune condition characterized by inflammation, growth, and damage to tissues around and behind the eye.

The THRIVE phase 3 clinical trial in active TED evaluated 5 infusions of veli or placebo every three weeks with primary topline analysis at week 15 and then followed patients through week 52.

## Positive Veligrotug Durability at 52 Weeks

- 70% of veligrotug patients (21/30) in THRIVE, who were proptosis responders at week 15 and continued follow-up to the end of the study at week 52, maintained their proptosis response. Maintenance of response is defined as responders at week 15 who still had at least a 2-millimeter (mm) reduction in proptosis compared to baseline at week 52, without worsening in the fellow eye ( $\geq 2$  mm increase), as measured by exophthalmometry.
- There were no changes to the safety profile in the follow-up period. The vast majority of adverse events reported at the week 15 primary analysis had resolved by week 52.

"We view the strength of today's durability and safety resolution data as reinforcing veli's strong and consistently robust clinical profile," said Steve Mahoney, Viridian's President and CEO. "We believe that the totality of veligrotug's clinical data continues to demonstrate its potential to be the treatment-of-choice for patients living with TED. We believe these data, together with a streamlined dosing regimen of five infusions, position veli to become a market leading TED therapeutic, if approved. We continue to make great progress towards submitting the BLA in the second half of this year and preparing for a potential launch in 2026."

## Robust Veligrotug Topline Clinical Profile for Active and Chronic TED

As announced in late 2024, veligrotug met all of its primary and secondary endpoints and was generally well-tolerated in its pivotal phase 3 clinical trials, THRIVE and THRIVE-2, for active and chronic TED, respectively. Veligrotug demonstrated a rapid onset of treatment effect and statistically significant and clinically meaningful reduction and resolution of diplopia in both clinical trials. THRIVE-2 was the first data set from a global phase 3 clinical trial in chronic TED patients to demonstrate statistically significant diplopia response and resolution. Together, THRIVE and THRIVE-2 comprise the largest pivotal program to date in TED.

## About Veligrotug

Veligrotug is an intravenously (IV) 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. IGF-1R is a clinically and commercially validated target for thyroid eye disease (TED) with U.S. revenues of approximately \$2 billion in 2024. Veligrotug has the potential to improve patient experience with a differentiated dosing regimen that features a shorter infusion time and fewer infusions compared to the currently approved and marketed IGF-1R inhibitor.

In its pivotal phase 3 clinical trials, THRIVE and THRIVE-2, veligrotug met all of its primary and secondary endpoints. Veligrotug demonstrated a rapid onset of treatment effect and statistically significant and clinically meaningful

reduction and resolution of diplopia in both clinical trials. THRIVE-2 was the first demonstration in a global phase 3 clinical trial of a statistically significant diplopia response and resolution in chronic TED patients. Veligrotug was generally well tolerated.

Viridian believes that the robust veligrotug clinical profile has the potential to establish a strong position in the TED commercial market, if approved, and may help facilitate the introduction of VRDN-003, its potential best-in-class subcutaneous IGF-1R antibody for TED.

## 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 is conducting 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 all the primary and 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 has the potential to be developed in multiple autoimmune diseases.

Viridian is based in Waltham, Massachusetts. For more information, please visit [www.viridiantherapeutics.com](http://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: clinical development and anticipated commercialization of Viridian's product candidates, including veligrotug (formerly VRDN-001) and VRDN-003; the potential utility, efficacy, potency, safety, clinical benefits, clinical response, convenience, and number of indications of veligrotug and VRDN-003, including Viridian's view of the strength of the THRIVE durability and safety resolution data and veligrotug's robust clinical profile; veligrotug's potential to be the IV treatment-of-choice for active and chronic TED; the impact of Breakthrough Therapy Designation, including eligibility for Priority Review, or any other FDA designations; regulatory interactions and anticipated timing of regulatory submissions, including the anticipated BLA submission for veligrotug in the second half of 2025; potential market sizes and market opportunities for Viridian's product candidates, including Viridian's belief that veligrotug is positioned to become a market leading TED therapeutic, if approved; Viridian's product candidates potentially being best-in-class; whether veligrotug will serve an unmet need; veligrotug's potential to improve patient experience over existing therapies; and Viridian's expectations regarding the potential commercialization of veligrotug and VRDN-003, if approved, including the potential U.S. launch of veligrotug in 2026.

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; 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 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.

**IR@viridiantherapeutics.com**

**Media@viridiantherapeutics.com**

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