

NEWS RELEASE

Viridian Therapeutics Announces Successful October Submission of Biologics License Application (BLA) to U.S. FDA for Veligrotug in Thyroid Eye Disease

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- BLA for veligrotug successfully submitted to the U.S. Food and Drug Administration (FDA) in late October following recent consultation with the agency -

- Veligrotug's Breakthrough Therapy Designation supports eligibility for potential Priority Review -

- FDA decision whether to accept the BLA for filing is expected within 60 days of submission -

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 the successful October submission of its BLA to the U.S. Food and Drug Administration (FDA) for veligrotug, the company's investigational therapy for the treatment of thyroid eye disease (TED). TED is a rare, debilitating autoimmune disorder characterized by inflammation and swelling of the tissues around the eyes, often leading to pain, vision impairment, and a significant reduction in quality of life. Veligrotug, a novel, fully human monoclonal antibody, has demonstrated promising results in pivotal clinical studies, with data showing improvement in proptosis, diplopia, and other key measures of disease activity and was generally well tolerated. Based on these results, veligrotug was granted Breakthrough Therapy Designation for the treatment of TED earlier this year.

"The submission of our BLA for veligrotug marks a major milestone for Viridian. Our team was able to submit the application despite the ongoing government shutdown following productive engagements with the FDA, reflecting our continued positive interactions with the agency to date," said Steve Mahoney, Viridian's President and CEO.

“This submission brings us one step closer to delivering a transformative therapy to people living with thyroid eye disease, as well as representing a key inflection point for Viridian as we transition toward a fully integrated commercial organization. We are grateful to the patients, investigators, our clinical partners, the FDA, and the entire Viridian team whose commitment has made this achievement possible.”

The BLA submission is supported by data from two pivotal phase 3 clinical trials, THRIVE and THRIVE-2, evaluating the efficacy and safety of veligrotug in patients with active and chronic TED, respectively. Both THRIVE and THRIVE-2 met all primary and secondary endpoints, and veligrotug was generally well tolerated. Veligrotug showed a rapid onset of clinical benefit and statistically significant and meaningful effect 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.

Viridian’s BLA includes a request for Priority Review, which if granted, could accelerate FDA’s review timing for a potential mid-2026 veligrotug commercial launch, if approved.

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 all the primary and secondary endpoints of each study. In these studies, veligrotug demonstrated a rapid onset of clinical benefit and statistically significant and clinically meaningful effect on multiple diplopia endpoints. This is the first data set from a global phase 3 clinical trial in chronic TED patients to demonstrate statistically significant diplopia response and resolution.

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) and a portfolio of inhibitors to the neonatal Fc receptor (FcRn). In TED, the company is conducting a pivotal program

for veligrotug, 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. 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 and review timelines; Viridian’s view that Breakthrough Therapy Designation may support eligibility for and potential receipt of Priority Review; veligrotug’s potential to be 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, including the potential U.S. launch of veligrotug in mid-2026, if approved.

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, including as a result of a prolonged government shutdown; the timing of and our ability to obtain, including as a result of a prolonged government shutdown, 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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