



NEWS RELEASE

Viridian Therapeutics Announces Completion of Enrollment in both REVEAL Clinical Trials and Positive Portfolio Updates

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- Enrollment complete in VRDN-003's phase 3 clinical trials in thyroid eye disease (TED), REVEAL-1 and REVEAL-2, with each study exceeding its enrollment target due to strong patient demand; topline data on track for first half of 2026 -
- VRDN-003 composition of matter patent granted by the USPTO with term to 2041 and potential to extend exclusivity -
- Veligrotag Biologics License Application (BLA) submission on track and anticipated in November 2025, enabling a mid-2026 commercial launch, if approved under Priority Review -
- VRDN-006 data in ongoing healthy volunteer study shows IgG reductions consistent with the FcRn inhibitor class and sparing of albumin and LDL; half-life extended VRDN-008 IND submission on track for year-end 2025 -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company focused on discovering, developing and commercializing potential best-in-class medicines for serious and rare diseases, today announced that enrollment is complete in REVEAL-1 and REVEAL-2, phase 3 clinical trials for VRDN-003 in patients with active and chronic TED, respectively. VRDN-003 is a subcutaneously delivered, half-life extended, monoclonal antibody targeting the insulin-like growth factor-1 receptor (IGF-1R).

"We are very pleased to continue Viridian's track record of strong enrollment in TED clinical trials with over 330 TED patients in these two studies, bringing the total number of TED patients participating in Viridian's clinical trials this

year to nearly 500,” said Steve Mahoney, Viridian’s President and Chief Executive Officer. “Both REVEAL-1 and REVEAL-2 are larger than their veligrotug counterparts, and REVEAL-2 is the largest global phase 3 clinical trial conducted in TED to date. Taken together with the majority of patients in each study enrolling from the US, we believe these to be strong signals of patient demand for VRDN-003. With veligrotug marching toward a BLA submission, and Breakthrough Therapy Designation supporting eligibility for Priority Review, we believe veligrotug and VRDN-003 have the potential to establish a new standard of care for patients. We would like to thank all the patients, caregivers, and clinical trial sites who are participating in our clinical studies.”

Thyroid Eye Disease (TED) Portfolio

VRDN-003 Enrollment Completed in REVEAL-1 and REVEAL-2

- REVEAL-1 and REVEAL-2 enrolled 132 and 204 patients respectively, each exceeding its target enrollments of 117 and 195 patients.
- 67% of REVEAL-1 patients were enrolled from the US, and 56% of REVEAL-2 patients were enrolled from the US.
- Topline data from both studies are on track for the first half of 2026; BLA submission planned for year-end 2026.
- Plan to launch VRDN-003, if approved, with a commercially validated, low-volume autoinjector allowing patients to self-administer at home.
- Composition of matter patent granted by the USPTO with term to 2041 and potential to extend exclusivity.

Veligrotug BLA Submission Anticipated in November 2025

- Anticipates submitting veligrotug BLA in November to the FDA.
- Breakthrough Therapy Designation, granted in May 2025, supports eligibility for Priority Review.
- Potential to commercially launch veligrotug in mid-2026, if approved under Priority Review.
- New patent granted for veligrotug method of use with term to 2042.

Neonatal Fc Receptor (FcRn) Inhibitor Portfolio

VRDN-006 Achieved IgG Reduction Proof-of-Concept in Healthy Volunteers

- VRDN-006, an Fc fragment which inhibits FcRn, showed IgG reductions in its ongoing phase 1 clinical trial that are consistent with the FcRn inhibitor class. VRDN-006 has to-date been generally well-tolerated, sparing of albumin and LDL, and showed no dose-limiting toxicities or serious adverse events.

VRDN-008 IND Submission on Track

- Investigational New Drug (IND) submission on track for year-end 2025. VRDN-008 showed a longer half-life and a more sustained IgG reduction head-to-head versus efgartigimod after a single, high dose in non-human primates.

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.

In its pivotal phase 3 clinical trials, THRIVE and THRIVE-2, veligrotug reported positive topline data, meeting all the primary and secondary endpoints of each study. Both THRIVE and THRIVE-2 demonstrated a rapid onset of treatment effect and statistically significant and clinically meaningful reduction and resolution of diplopia. 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 VRDN-003

VRDN-003 is a subcutaneously delivered, half-life extended, potential best-in-class anti-IGF-1R antibody. VRDN-003 has the same binding domain as veligrotug and was engineered to have a longer half-life. In a phase 1 healthy volunteer clinical trial, VRDN-003 showed a half-life of 40-50 days, 4-5x that of veligrotug. Pharmacokinetics modeling predicted that VRDN-003 exposure levels after Q4W and Q8W dosing achieve the range of veligrotug exposures that showed robust clinical activity in a two-infusion phase 2 clinical trial in TED. Viridian is conducting a pivotal program for VRDN-003, including two phase 3 clinical trials assessing VRDN-003 dosed Q4W and Q8W in active and chronic TED, REVEAL-1 and REVEAL-2, respectively. Viridian believes that VRDN-003 has the potential to expand the multi-billion-dollar TED commercial market as a potential best-in-class subcutaneous IGF-1R antibody for TED.

About VRDN-006 and VRDN-008

VRDN-006 is a highly selective Fc fragment which inhibits FcRn and is designed to be a convenient subcutaneous and self-administered option for patients. Viridian is studying VRDN-006 in a first-in-human phase 1 clinical trial in healthy volunteers.

VRDN-008 is a half-life extended FcRn inhibitor comprising an Fc fragment and an albumin-binding domain designed to prolong IgG suppression and provide a potentially best-in-class subcutaneous option for patients.

VRDN-008 showed a longer half-life than efgartigimod and led to a more sustained IgG reduction after a single, high dose in non-human primates in a head-to-head study.

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. 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 (formerly VRDN-001), VRDN-003, VRDN-006, and VRDN-008; anticipated data results and timing of their disclosure, including VRDN-003 topline data from the REVEAL-1 and REVEAL-2 trials in the first half of 2026; regulatory interactions and anticipated timing of regulatory submissions, including the anticipated BLA submission for

veligrotug in November 2025 and VRDN-003 by year-end 2026, and IND submission for VRDN-008 by year-end 2025, pending data; the impact of Breakthrough Therapy Designation, including eligibility for Priority Review, or any other FDA designations; the potential to obtain an extension of exclusivity on our U.S. composition of matter patent for VRDN-003; the potential utility, efficacy, potency, safety, clinical benefits, clinical response, convenience, and number of indications of veligrotug, VRDN-003, VRDN-006, and VRDN-008; veligrotug's potential to be the IV treatment-of-choice for active and chronic TED; the potential of veligrotug and VRDN-003 to establish a standard of care for patients; potential market sizes and market opportunities for Viridian's product candidates, including Viridian's beliefs regarding the strength of patient demand for VRDN-003 and its ability to expand the TED commercial market; Viridian's product candidates potentially being best-in-class, including Viridian's view of VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED; and Viridian's expectations regarding the potential commercialization of veligrotug and VRDN-003, if approved, including the potential U.S. launch of veligrotug in mid-2026 if approved under Priority Review and plans to launch VRDN-003 with a low-volume autoinjector.

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.

Source: Viridian Therapeutics, Inc.

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Source: Viridian Therapeutics, Inc.