



NEWS RELEASE

Viridian Therapeutics Announces Details of Subcutaneous VRDN-003 Phase 3 Clinical Program for Patients with Active and Chronic Moderate-to-Severe Thyroid Eye Disease

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- On track to initiate two phase 3 clinical trials of VRDN-003 in August 2024 -

- REVEAL-1 and REVEAL-2, will evaluate two active dosing regimens of subcutaneously (SC) administered VRDN-003 in active and chronic thyroid eye disease (TED), with topline readout anticipated in the first half of 2026 for both trials -

- VRDN-003 Biologics License Application (BLA) submission anticipated by year-end 2026 -

- VRDN-003 is the only half-life extended anti-IGF-1R antibody in clinical development with the potential for convenient SC dosing as infrequently as every 8 weeks, for a total of 3 administrations -

WALTHAM, Mass.--(BUSINESS WIRE)-- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company focused on discovering and developing potential best-in-class medicines for serious and rare diseases, today reported details of its plans to initiate a phase 3 clinical trial program for its SC VRDN-003 product candidate for patients with moderate-to-severe TED.

"We are very pleased to have completed a positive Type C meeting with the FDA and to take this next step towards rapidly bringing a highly differentiated treatment option to patients living with TED," said Steve Mahoney, Viridian's President and Chief Executive Officer. "We view VRDN-003 as a potentially best-in-class anti-IGF-1R product candidate that is designed to preserve the compelling IGF-1R clinical response we have seen in our earlier proof-of-

concept studies of VRDN-001. We believe this product profile could maximize convenience as a low-volume, infrequent subcutaneous injection and provide better access to treatment for patients.”

Phase 3 Clinical Trials in Active and Chronic TED

Viridian is planning to initiate two randomized, double-masked, placebo-controlled phase 3 clinical trials designed to evaluate the efficacy and safety of subcutaneously administered VRDN-003 in patients with active and chronic TED, named REVEAL-1 and REVEAL-2, respectively. These clinical trials are expected to initiate in August 2024.

In REVEAL-1, approximately 84 patients will be randomized in a 1:1:1 ratio to receive VRDN-003 SC or placebo every 4 weeks or every 8 weeks. Patients will receive an initial 600mg loading dose given as two 300mg injections, followed by single injections of 300mg thereafter for a total of 6 administrations in the 4-week dosing regimen and a total of 3 administrations in the 8-week regimen. In REVEAL-2, approximately 126 patients will be randomized in the same manner for the same dosing regimens. The primary endpoint in each clinical trial will be proptosis responder rate, based on the achievement of at least 2mm improvement in proptosis from baseline at week 24, versus placebo. Subsequently, patients will be followed for an additional 28 weeks. Additional outcome measures in each trial will include changes from baseline in proptosis, clinical activity score (CAS) and diplopia.

“The current standard of care in TED requires 8 intravenous doses, representing a significant burden for patients,” said Tom Ciulla, Viridian’s Chief Medical Officer. “Subcutaneous VRDN-003 could transform the treatment experience for patients with TED.”

Viridian anticipates topline data for both clinical trials to be available in the first half of 2026 and to file a BLA by the end of 2026. The company plans to launch VRDN-003 with a commercially available autoinjector pen.

About VRDN-003

VRDN-003 is a potential best-in-class, subcutaneously administered anti-IGF-1R antibody in development for TED. VRDN-003 has the same binding domain as VRDN-001, was engineered to have a longer half-life, and acts as a full antagonist of IGF-1R. IGF-1R inhibition is the only approved mechanism of action that has been clinically and commercially validated for TED and has shown to be highly effective in treating the disease.

Phase 1 results in healthy volunteers showed a VRDN-003 half-life of 40-50 days which is 4-5x the half-life of VRDN-001. Further, pharmacokinetic modeling predicts that convenient dosing regimens of VRDN-003 (e.g., a low volume subcutaneous injection once every 4 or 8 weeks) could achieve exposure levels of VRDN-003 that are equivalent to those of VRDN-001 that produced clinically meaningful results in TED patients in a phase 2, proof-of-concept clinical trial.

About Viridian Therapeutics

Viridian is a biopharmaceutical company focused on engineering and developing 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 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. Viridian is also advancing VRDN-003 as a potential best-in-class subcutaneous therapy for the treatment of TED and is planning to initiate a global phase 3 program, REVEAL and REVEAL-2, to evaluate the efficacy and safety of VRDN-003 in patients with active and chronic TED, respectively.

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," "continue," "could," "estimate," "expect," "intend," "may," "might," "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 programs or clinical development of Viridian's product candidates; anticipated start dates and designs of studies, including the REVEAL-1 and REVEAL-2 clinical trials; regulatory interactions and anticipated regulatory submissions, including the anticipated BLA filing for VRDN-003; upcoming milestones and anticipated data results, including topline results; plans to launch VRDN-003 with a commercially available autoinjector pen; VRDN-003 preserving the compelling IGF-1R clinical response and exposure levels seen in Viridian's earlier proof-of-concept studies of VRDN-001; enrollment in Viridian's clinical studies; anticipated dosing frequency; the potential utility, efficacy, potency, safety, clinical benefits, clinical response and convenience of VRDN-001, VRDN-003, VRDN-006 and VRDN-008; and Viridian's product candidates potentially being best-in-class.

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; the relationship between the results from the positive data from completed or ongoing clinical trials and 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; trial protocols for ongoing clinical trials; expectations regarding the timing for regulatory filings; regulatory interactions; expectations 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; Viridian's intellectual property position; the timing of preclinical and clinical trial activities and reporting results from same; and those risks set forth under the caption "Risk Factors" in our most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 8, 2024 and other subsequent disclosure documents filed with the SEC. 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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