Viridian Therapeutics Announces First Patient Enrolled in the ‘THRIVE’ Phase 3 Trial in Patients With Thyroid Eye Disease

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- The global THRIVE Phase 3 trial will be conducted in approximately 50 centers across North America and Europe -

- Topline results for the THRIVE Phase 3 trial are expected in the middle of 2024 –

WALTHAM, Mass., Dec. 21, 2022 (GLOBE NEWSWIRE) -- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biopharmaceutical company focused on discovering and developing potential best-in-class medicines for serious and rare diseases, today announced that the first patient has been enrolled in its THRIVE Phase 3 trial evaluating the efficacy and safety of the investigational agent VRDN-001 in patients with active thyroid eye disease (TED). The global THRIVE Phase 3 trial will be conducted in approximately 50 centers across North America and Europe.

"We are pleased to enroll the first patient in the THRIVE trial, which is designed to confirm the compelling early results we’ve seen in TED patients," said Jonathan Violin, Ph.D., President and Chief Executive Officer of Viridian Therapeutics. "The study is a significant milestone for Viridian, and reinforces our commitment to the TED community. It is an important and meaningful step in our efforts to provide new and improved treatment options to patients with TED."

The THRIVE Phase 3 trial is a double-blind, placebo-controlled, randomized study enrolling approximately 120 patients with active TED. The study participants will be randomized 1:1:1 across three arms: VRDN-001 10 milligrams per kilogram administered once every three weeks for eight cycles, an accelerated course of VRDN-001 10 milligrams per kilogram administered once every three weeks for five cycles, and a placebo arm.

The primary efficacy endpoint for THRIVE is proptosis (eye bulging) responder rate, defined as the proportion of patients who achieve a reduction of proptosis of at least 2 millimeters compared to baseline at week 24. Secondary endpoints include overall response rate, change in proptosis as measured by exophthalmometer and magnetic resonance imaging (MRI), change in clinical activity score, and rate of diplopia resolution. Following week 24, trial participants may roll over into an open-label extension study followed by a longer-term registry study.

The Company is also planning a second global Phase 3 trial in patients with chronic TED called THRIVE-2. The THRIVE and THRIVE-2 Phase 3 trials will support global health authority registration for marketing approval in both active and chronic TED.

VRDN-001 is an investigational therapy not approved for any use in any country.

About Viridian’s Thyroid Eye Disease Pipeline (VRDN-001, -002, and -003)

Viridian’s lead product candidate, VRDN-001, is a differentiated monoclonal antibody targeting insulin-like growth factor-1 receptor (IGF-1R), a clinically and commercially validated target for the treatment of thyroid eye disease (TED). In preclinical studies, VRDN-001 was shown to be a full antagonist of IGF-1R, with more complete receptor blockade than other anti-IGF-1R antibodies, including the only currently approved TED therapy. Data from the initial dose cohorts of the Phase 2 portion of the ongoing trial established clinical proof-of-concept for VRDN-001 in patients with active TED. Preliminary data from the ongoing trial showed treatment with VRDN-001 led to reductions in proptosis, clinical activity score (CAS), and diplopia resolution. VRDN-001 was generally safe and well tolerated in the trial. The Company recently initiated its THRIVE Phase 3 trial in patients with active TED to support global marketing registration.

VRDN-001 is also being evaluated in Phase 2 trial cohorts in patients with chronic TED. Pending positive results, the Company plans to start its THRIVE-2 Phase 3 trial in patients with chronic TED.

The Company is also advancing VRDN-002, a distinct anti-IGF-1R antibody incorporating half-life extension technology, and VRDN-003, a half-life extended version of VRDN-001. Both VRDN-002 and VRDN-003 are designed for administration as convenient, low-volume, subcutaneous injections.

VRDN-001, -002, and -003 are investigational therapies that are not approved for any use in any country.

About TED

TED is a serious and debilitating rare autoimmune disease that causes inflammation within the orbit of the eye that can cause double vision, pain, and potential blindness. TED is a progressive disease consisting of an initial active phase, followed by a transition to a secondary chronic phase. More than 50,000 and 200,000 people are estimated to suffer from active and chronic TED, respectively, in the United States and Europe.

About Viridian Therapeutics

Viridian Therapeutics 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 engineering enables it to develop 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 recently initiated its first global Phase 3 trial called ‘THRIVE’ to evaluate the safety and efficacy of VRDN-001 in patients with active TED. Viridian is also evaluating VRDN-001 in a Phase 2 proof-of-concept trial in patients with chronic TED. In addition to its intravenously administered VRDN-001 program, the Company is advancing two candidates for its subcutaneous strategy with the goal of providing a more conveniently administered therapy to patients with TED. Viridian is developing multiple preclinical assets in autoimmune and rare diseases.

Viridian is based in Waltham, Massachusetts. For more information, please visit https://www.viridiantherapeutics.com. Follow Viridian on LinkedIn.

Note Regarding 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 include, without limitation, statements regarding the Company's expectations and guidance regarding its global Phase 3 clinical trial plans for VRDN-001, the timing and nature of the initial results from its global Phase 3 THRIVE trial and the therapeutic potential of VRDN-001 as compared to other therapies. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations, and assumptions. 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: uncertainty and potential delays related to clinical drug development; the duration and impact of regulatory delays in our clinical programs; manufacturing risks; competition from other therapies or products; other matters that could affect the sufficiency of existing cash, cash equivalents and short-term investments to fund operations; the Company's future operating results and financial performance; the timing of pre-clinical and clinical trial activities and reporting results from same; the effects from the COVID-19 pandemic on the Company's research, development and business activities and operating results, including those risks set forth under the caption "Risk Factors" in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 11, 2022 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 we, nor our 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 our views as of any date subsequent to the date hereof.

Investor and Media Contact:
Todd James
Viridian Therapeutics, Inc.
Senior Vice President, Corporate Affairs and Investor Relations
IR@viridiantherapeutics.com

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