Viridian Therapeutics Announces First Subject Dosed in Phase 1/2 Clinical Trial of VRDN-001 for Thyroid Eye Disease (TED)

December 20, 2021

- VRDN-001 targets and blocks IGF-1R, the only mechanism of action proven to deliver efficacy in TED -
- Trial is on track to deliver top line proof of concept clinical data in 2Q 2022 -

WALTHAM, Mass., Dec. 20, 2021 (GLOBE NEWSWIRE) -- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biotechnology company advancing new treatments for patients suffering from serious diseases underserved by current therapies, today announced the first subject was dosed in a Phase 1/2 proof-of-concept clinical trial for VRDN-001, a monoclonal antibody that blocks the IGF-1 receptor with sub-nanomolar potency. IGF-1R blockade is a clinically validated mechanism of action for the treatment of TED.

The Phase 1/2 trial is designed to evaluate safety, tolerability, pharmacokinetics, and potential efficacy of VRDN-001. The trial includes both healthy volunteers and randomized, placebo-controlled cohorts of TED patients and will assess multiple measures of the signs and symptoms of TED, including proptosis – the bulging of eyes characteristic of TED. The Company expects to announce top line data from the proof-of-concept portion of the trial in the second quarter of 2022. The trial protocol allows for additional TED patient cohorts to assess differing treatment paradigms that may offer advantages over currently available therapies and may reduce the burden of patient treatment.

“We are excited to initiate our first clinical trial of VRDN-001. This trial is designed to quickly assess the potential of VRDN-001 to offer a new option for patients suffering from TED, and to inform how we can optimize VRDN-001 development to best meet patients’ needs,” stated Jonathan Violin, Ph.D., Viridian Therapeutics’ President and CEO. “VRDN-001 exemplifies Viridian’s patient-centric model of innovation that leverages proven biology and technology to efficiently craft medicines to meet the needs of patients and healthcare providers.”

The clinical development plan for VRDN-001 was informed by safety, tolerability, pharmacokinetic, and pharmacodynamic data from more than 100 oncology patients who were previously administered this antibody under the name AVE1642.

About Viridian Therapeutics, Inc.

Viridian Therapeutics is a biotechnology company advancing new treatments for patients suffering from serious diseases but underserved by today’s therapies. Viridian’s most advanced program, 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). Viridian’s second product candidate, VRDN-002, is a distinct anti-IGF-1R antibody that incorporates half-life extension technology and is designed to support administration as a convenient, low-volume, subcutaneous injection. TED is a debilitating autoimmune disease that causes inflammation and fibrosis within the orbit of the eye which can cause double vision, pain, and potential blindness. Patients with severe disease often require multiple remedial surgeries to the orbit, eye muscles and eyelids. Viridian is based in Waltham, Massachusetts.

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 clinical trial plans for VRDN-001, the timing and nature of the initial results from such trials, 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; the timing of 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 5, 2021 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.

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