Viridian Therapeutics Doses First Subject in First-in-Human Clinical Trial Evaluating VRDN-002, a Next Generation IGF-1R Antibody for the Treatment of Thyroid Eye Disease

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- VRDN-002 incorporates clinically validated half-life extension technology to support development as a low volume subcutaneous injection that could broaden settings of care -

- Top line results from the Phase 1 trial of VRDN-002 expected mid-year -

WALTHAM, Mass., March 21, 2022 (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 that it has dosed the first subject in a Phase 1 clinical trial evaluating VRDN-002 for the treatment of thyroid eye disease (TED).

This is a first-in-human Phase 1 clinical trial of VRDN-002, a humanized monoclonal antibody that incorporates half-life extension technology and is designed to support administration as a convenient, low-volume, subcutaneous (SC) injection for the treatment of TED patients. The single ascending dose trial will explore safety, tolerability, pharmacokinetics and pharmacodynamics of intravenously administered VRDN-002 at doses of 3, 10, and 20 mg/kg in up to 16 healthy volunteers. Topline data from the trial are expected to be announced mid-year and will inform the feasibility of a low-volume SC dosing paradigm for TED patients.

“With VRDN-001 and VRDN-002, we are focused on developing a portfolio approach to advance patient care for TED patients. The initiation of this first-in-human trial of VRDN-002 delivers a key milestone as we execute our development strategy for VRDN-002 and ramp up clinical activity across our pipeline,” stated Jonathan Violin, Ph.D., Viridian Therapeutics’ President and CEO. “Incorporating half-life extension technology that may enable SC administration is a significant step forward in the treatment of TED. The option of a SC injection would broaden the settings of care, either at home by patients via self-administration or in the prescribing physician’s office.”

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 humanized 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-002, the timing and nature of the initial results from such trial and the therapeutic potential of VRDN-001 and VRDN-002, 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.

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