# Viridian Therapeutics Announces FDA Clearance of Investigational New Drug Application to Initiate Clinical Development of 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 -*
*- Company expects to report top line VRDN-002 Phase 1 clinical data in mid-2022 -*

WALTHAM, Mass., Jan. 31, 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 the United States Food and Drug Administration (FDA) clearance of its investigational new drug (IND) application of VRDN-002. The Company's next generation IGF-1R antibody, VRDN-002, is 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 thyroid eye disease (TED).

The IND application clearance allows the Company to proceed with its planned first-in-human Phase 1 clinical trial of VRDN-002, which is a single ascending dose study to explore safety, tolerability, pharmacokinetics and pharmacodynamics of intravenously administered VRDN-002 in healthy volunteers. Data from this Phase 1 trial are expected to be announced in mid-2022 and will inform the feasibility of a low-volume and/or low-frequency SC dosing paradigm for TED patients.

"We are excited to advance our VRDN-002 clinical development plan. We believe the incorporation of half-life extension technology into VRDN-002 may enable a differentiated, low volume subcutaneous injection, offering TED patients improved convenience and broader settings of care," stated Jonathan Violin, Ph.D., Viridian Therapeutics' President and CEO. "This IND acceptance is the first of multiple regulatory, clinical, and operational milestones expected in 2022, including top-line data from our VRDN-001 Phase 1/2 proof of concept trial in the second quarter of 2022, and top-line data from our VRDN-002 Phase 1 trial in mid-2022."

**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 and VRDN-002, the timing and nature of the initial results from such trials, 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; 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.

**Investor and Media Contact:**
John Jordan
Viridian Therapeutics
Vice President, Investor Relations
& Corporate Communications
617-272-4691
IR@viridiantherapeutics.com