



Viridian Therapeutics Announces FDA Clearance of Investigational New Drug (IND) Application for VRDN-001, an IGF-1R Antibody for the Treatment of Thyroid Eye Disease (TED)

November 15, 2021

- *Phase 1/2 proof of concept trial for VRDN-001 is expected to report top line clinical data in the second quarter of 2022*

WALTHAM, Mass., Nov. 15, 2021 (GLOBE NEWSWIRE) -- Viridian Therapeutics, Inc. (NASDAQ: VRDN) (the "Company" or "Viridian"), a biotechnology company advancing new treatments for patients suffering from serious diseases underserved by current therapies, today announced the U.S. Food and Drug Administration ("FDA") clearance of its Investigational New Drug ("IND") application for VRDN-001, which the Company is developing for the treatment of thyroid eye disease (TED).

VRDN-001 is a monoclonal antibody that binds and blocks the IGF-1R signaling pathway with sub-nanomolar affinity. This mechanism of action is clinically and commercially validated for the treatment of TED. The Company's first clinical trial for VRDN-001 is a Phase 1/2 proof of concept trial including multiple randomized, placebo-controlled cohorts of TED patients to assess the potential for VRDN-001 to provide rapid improvement of signs and symptoms of TED, including proptosis. The protocol for this trial allows for additional patient cohorts to assess differing treatment paradigms that may offer advantages over currently available therapies and mitigate patient treatment burden. The Company expects to announce top line data from the proof of concept portion of the trial in the second quarter of 2022.

"Our first clinical trial for VRDN-001 is designed to rapidly test proof of concept while enabling data-driven evaluation of dosing paradigms that could offer TED patients new and differentiated therapeutic options. With the IND accepted by the FDA, we remain on track to report top line clinical data for VRDN-001 in the second quarter of 2022," stated Jonathan Violin, Ph.D., Viridian's President and CEO. "This is the first milestone in what we expect to be a busy 12 months as we advance the development of our clinical and preclinical pipeline of potential best in class therapeutics."

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). 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.

Viridian Contacts:

Investors:

Dan Ferry
LifeSci Advisors
617-430-7576
IR@viridiantherapeutics.com

Media:

Darby Pearson
Verge Scientific Communications
703-587-0831
PR@viridiantherapeutics.com