Viridian Therapeutics Submits Investigational New Drug Application for VRDN-001, an IGF-1R antibody for the treatment of Thyroid Eye Disease, to the U.S. Food and Drug Administration

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- VRDN-001 program remains on track for key proof of concept clinical data in Thyroid Eye Disease patients in the second quarter of 2022 -

WALTHAM, Mass., Oct. 14, 2021 (GLOBE NEWSWIRE) -- Viridian Therapeutics, Inc. (NASDAQ: VRDN), a biopharmaceutical company advancing new treatments for patients suffering from serious diseases underserved by today's therapies, announced today the submission of an investigational new drug (IND) application to the United States Food and Drug Administration (FDA). The Company is seeking authorization to initiate a Phase 1/2 clinical trial of VRDN-001, an anti-insulin-like growth factor-1 receptor (IGF-1R) monoclonal antibody in development for the treatment of thyroid eye disease (TED), a debilitating disease that can cause proptosis (bulging eyes), double vision, and potential blindness.

The Company believes this clinical trial could provide key proof of concept clinical data in TED patients, with the potential to show clinically meaningful improvements in signs and symptoms of TED, including proptosis. The Company expects to announce top line clinical data from the proof of concept portion of the proposed trial in the second quarter of 2022.

“Our IND filing is an important milestone as we continue to advance the development of VRDN-001 as a potential treatment for patients suffering from Thyroid Eye Disease. We look forward to launching this trial upon IND activation,” stated Jonathan Violin, Ph.D., President and Chief Executive Officer of Viridian. “Our IND submission features a trial protocol designed to rapidly evaluate proof of concept, with flexibility to subsequently assess different doses and treatment regimens that may differentiate VRDN-001 from currently available therapies.”

About VRDN-001

VRDN-001, Viridian’s lead TED program, is an intravenously administered anti-IGF-1R monoclonal antibody. This antibody was previously in development as AVE1642 and was studied in more than 100 oncology patients. The pharmacokinetic, pharmacodynamic, safety, and tolerability data from the AVE1642 program inform Viridian’s development plans for VRDN-001.

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 regarding its clinical trial plans for VRDN-001, the activation of the Company’s IND for VRDN-001 by the FDA, 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: the satisfaction of customary closing conditions related to the proposed underwritten public offering; and other risks and uncertainties identified in our filings with the SEC, 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 August 12, 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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