



Voyager Therapeutics Provides Regulatory Update on VY-HTT01 Program

10/12/20

CAMBRIDGE, Mass., Oct. 12, 2020 (GLOBE NEWSWIRE) -- Voyager Therapeutics, Inc. (NASDAQ: VYGR), a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases, today announced that it has received feedback from the U.S. Food and Drug Administration (FDA) on the Investigational New Drug (IND) submission for VY-HTT01 for the treatment of Huntington's disease. Voyager submitted the IND for VY-HTT01 in September 2020 and has been notified that the IND was placed on clinical hold pending the resolution of certain chemistry, manufacturing and controls (CMC) matters. The Company expects to receive specific feedback from the FDA on these matters within 30 days and plans to work closely with the agency to resolve them and promptly begin the clinical evaluation of VY-HTT01.

About VY-HTT01

Huntington's disease is a fatal, inherited neurodegenerative disease that causes the progressive breakdown of nerve cells in the brain, resulting in a range of motor, cognitive, and psychiatric symptoms. Symptom onset typically occurs between the ages of 30 to 50 and the average length of survival after clinical diagnosis is typically 10 to 20 years. Huntington's disease is the most common monogenic neurological disorder in the developed world and is estimated to affect over 40,000 people in the U.S. Currently, there are no approved treatments targeting the underlying cause of the disease.

About Voyager Therapeutics

Voyager Therapeutics is a clinical-stage gene therapy company focused on developing life-changing treatments for severe neurological diseases. Voyager is committed to advancing the field of AAV gene therapy through innovation and investment in vector engineering and optimization, manufacturing, and dosing and delivery techniques. Voyager's wholly owned and partnered pipeline focuses on severe neurological diseases for which effective new therapies are needed, including Parkinson's disease, Huntington's disease, Friedreich's ataxia, and other severe neurological diseases. For more information on Voyager Therapeutics, please visit the company's website at www.voyagertherapeutics.com or follow [@VoyagerTx](https://twitter.com/VoyagerTx) on Twitter and [LinkedIn](https://www.linkedin.com/company/voyager-therapeutics).

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "may," "might," "will," "would," "should," "expect," "plan," "anticipate," "believe," "estimate," "undoubtedly," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward-looking statements. For example, all statements Voyager makes regarding the FDA advice that the FDA will provide feedback regarding Voyager's IND filing with the FDA for VY-HTT01 within 30 days and Voyager's expectation to initiate activities to address CMC matters promptly are each forward looking statements. All forward-looking statements are based on estimates and assumptions by Voyager's management that, although Voyager believes such forward-looking statements to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Voyager expected. Such risks and uncertainties include, among others, the timely delivery of feedback from the FDA with respect to Voyager's IND application for VY-HTT01 and the ability of Voyager to initiate activities in response to the CMC matters and to successfully complete those activities promptly. These statements are also subject to a number of material risks and uncertainties that are described in Voyager's Annual Report on Form 10K, Voyager's Quarterly Reports on Form 10-Q and other reports filed by Voyager with the Securities and Exchange Commission, as may be updated by its subsequent filings with the Securities and Exchange Commission. All information in the press release is as of the date of this press release, and any forward-looking statement speaks only as of the date on which it was made. Voyager undertakes no obligation to publicly update or revise this information or any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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Source: Voyager Therapeutics, Inc.