Voyager Therapeutics Provides Update on NBIb-1817 (VY-AADC) Gene Therapy Program

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CAMBRIDGE, Mass., Feb. 02, 2021 (GLOBE NEWSWIRE) -- Voyager Therapeutics, Inc. (Nasdaq: VYGR) today announced that Neurocrine Biosciences, Inc. (Nasdaq: NBIX) provided notice of termination of the Parkinson's disease portion of the collaboration agreement, effective August 2, 2021. The Friedreich's ataxia program and two discovery programs that are also part of the agreement are not impacted and remain under active collaboration.

Voyager's understanding is that Neurocrine's decision to terminate the NBIb-1817 (VY-AADC) program was based on a portfolio review and prioritization of its current pipeline assets. Voyager plans to support Neurocrine, the IND holder and sponsor of the RESTORE-1 Phase 2 clinical trial, on any ongoing matters related to additional imaging and clinical assessments requested by the Data Safety & Monitoring Board (DSMB) and other information that may be requested by the U.S. Food and Drug Administration (FDA).

In December 2020, Voyager announced that the FDA had notified Neurocrine that it had placed a clinical hold on the RESTORE-1 clinical trial of NBIb-1817 (VY-AADC). The FDA notification followed a request by the study's independent DSMB for a pause in dosing pending the receipt of information about magnetic resonance imaging (MRI) abnormalities observed in trial participants. In January 2021, the FDA informed Neurocrine of the information required to provide a complete response to the FDA in connection with the clinical hold. Information required by the FDA includes an assessment of how the investigational product may have given rise to the adverse findings, a mitigation plan to manage the adverse findings, and supportive data to justify that a favorable benefit/risk profile remains for the product.

Voyager is evaluating the complete financial impact of the termination and the future of the Parkinson's program and expects to provide a subsequent update.

About Parkinson's Disease and NBIb-1817 (VY-AADC)
Parkinson's disease is a chronic, progressive, and debilitating neurodegenerative disease that affects approximately one million people in the U.S. and ten million people worldwide. It is characterized by a loss of dopamine and neuronal degeneration with a concomitant loss of the aromatic L-amino acid decarboxylase (AADC) enzyme required to synthesize dopamine in the brain, leading to associated impairment in motor, neuropsychiatric, and autonomic functions. Dopamine is a chemical "messenger" that is produced in the brain and is involved in the control of movement. It is made when AADC converts the chemical levodopa to dopamine. As Parkinson's disease progresses, there is less AADC enzyme in parts of the brain where levodopa is converted to dopamine.

NBIb-1817 (VY-AADC) is an investigational recombinant adeno-associated viral (AAV) serotype 2 vector encoding the gene for human AADC that is designed to help produce the AADC enzyme in brain cells where it can convert levodopa to dopamine. NBIb-1817 (VY-AADC) is administered into the brain using intraoperative monitoring with magnetic resonance imaging (MRI)-facilitated targeted delivery.

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 on Twitter and LinkedIn.

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 progress, activities, goals and reporting of results of its clinical trials, the potential benefits and future operation of its collaboration with Neurocrine and the activities thereunder, Voyager's ability to perform its obligations under the collaboration agreement with Neurocrine, the ability of Neurocrine and Voyager to gather additional information to further characterize the safety profile of NBIb-1817 (VY-AADC) and to work with the FDA to determine the next steps for the RESTORE-1 clinical trial, the regulatory pathway of, and the timing or likelihood of its regulatory filings and approvals for, any of Voyager's product candidates, and its anticipated financial results, including the financial impact of the termination of the NBIb-1817 (VY-AADC) program, are forward looking.

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, those related to the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the expectations for regulatory communications, submissions and approvals; the continued development of the gene therapy platform and its TRACER system; Voyager's scientific approach and general development progress; the sufficiency of its cash resources; the availability or commercial potential of Voyager's product candidates; and the ability of Neurocrine and Voyager to complete their evaluation and to meet the information requests of, and to resolve questions raised by, the FDA required to bring an end to the clinical hold on the RESTORE-1 clinical trial. These statements are also subject to a number of material risks and uncertainties that are described in Voyager's Annual Report on Form 10-K filed with the Securities and Exchange Commission, as 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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