Voyager Therapeutics Enters into Strategic Manufacturing Collaborations with Brammer Bio and Fujifilm Diosynth Biotechnologies

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Collaborations to provide Voyager the ability and flexibility to transfer its manufacturing expertise across multiple high-quality vendors to support the development of its pipeline programs

CAMBRIDGE, Mass., Nov. 29, 2018 (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 entered into collaborations with Brammer Bio (Brammer) and Fujifilm Diosynth Biotechnologies (Fujifilm) to further expand Voyager's manufacturing capabilities to support the development of its gene therapy programs. The collaborations allow Voyager to transfer its state-of-the-art research and development production capabilities to best-in-class gene therapy contract development and manufacturing organizations (CDMO) with late-stage clinical and commercial-scale capabilities, particularly as it relates to the baculovirus/Sf9 system for manufacturing adeno-associated virus (AAV) gene therapies.

"Collaborating with Brammer and Fujifilm fits squarely within our manufacturing strategy to build strong internal preclinical and clinical processes, analytical development, and scale-up expertise and to partner with quality CDMOs for larger scale, redundant supply and commercial-stage capacity," said Luis Maranga, Ph.D., chief technical operations officer at Voyager Therapeutics. "Brammer and Fujifilm have recently completed renovations and launches of late-stage and commercial-ready facilities for gene therapy products in Cambridge, Massachusetts and College Station, Texas, respectively, and we are ready to begin working with them to support the advancement of our pipeline programs."

Voyager's manufacturing and related intellectual property strategy focuses on developing internal processes and capabilities to produce high-yield and high-quality gene therapies, including the use of the baculovirus/Sf9 AAV production system, with the potential to transfer these capabilities to increase capacity and scale through the use of external CDMOs. As part of today's announcement, Voyager will partner with Brammer to implement a commercial-ready manufacturing process under current good manufacturing practice (cGMP) at their Cambridge facility, and will partner with Fujifilm to provide first-in-human cGMP clinical trial material production capacity at their College Station facility.

"Today's announcement with Voyager represents a continued commitment to our vision to enable innovators to bring advanced medicines to patients," said Mark Bamforth, president and chief executive officer of Brammer. "Our recently announced progress on a three-year, $200 million investment program to establish over 30 suites for clinical and commercial viral vector supply in Alachua, Florida, and Cambridge and Lexington, Massachusetts, by 2019, uniquely positions Brammer to support the dramatic anticipated growth of the gene and cell therapy sector, including Voyager's pipeline of AAV gene therapy programs."

"We are thrilled to begin working with Voyager and to be a contributor to the development of their gene therapy pipeline," said Gerry Farrell, chief operating officer of Fujifilm Diosynth Biotechnologies, Texas. "These therapies have the potential of transforming patients' lives and, as an organization, we are delighted to support our partners as they advance tomorrow's medicines."

Voyager Therapeutics' Recent Manufacturing Data at ASGCT/ESGCT

Voyager's manufacturing platform utilizes a baculovirus/Sf9 cell production process that enables the production of AAV vectors at clinical and commercial scale, with the potential for increased yields over traditional production processes. Presentations at this year's American Society for Gene and Cell Therapy (ASGCT) conference in May (link here) included data from a cleared investigational new drug (IND) application for Voyager's VY-AADC for Parkinson's disease demonstrating comparability between VY-AADC produced under (GMP) using Voyager's baculovirus/Sf9 manufacturing process and VY-AADC produced using a mammalian cell system consisting of triple-transfection of human embryonic kidney (HEK293) cells. These data demonstrated that the baculovirus/Sf9 production system can be used to produce AAV vectors that are comparable with respect to bio-distribution, potency and expression in vivo compared to AAV vectors produced in mammalian cells.

Data at this year's European Society for Gene and Cell Therapy (ESGCT) conference in October (link here) further demonstrated Voyager's strong molecular biology capabilities and robustness of the baculovirus/Sf9 platform to produce high quality AAV gene therapies through various methodologies including precise modulation of novel capsid protein stoichiometry.

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 pipeline focuses on severe neurological diseases in need of effective new therapies, including Parkinson's disease, a monogenic form of ALS called SOD1, Huntington's disease, Friedreich's ataxia, neurodegenerative diseases related to defective or excess aggregation of tau protein in the brain including Alzheimer's disease and severe, chronic pain. Voyager has broad strategic collaborations with Sanofi Genzyme, the specialty care global business unit of Sanofi, AbbVie, and the University of Massachusetts Medical School. Founded by scientific and clinical leaders in the fields of AAV gene therapy, expressed RNA interference and neuroscience, Voyager Therapeutics is headquartered in Cambridge, Massachusetts.

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 initiation, timing, progress and reporting of results of its preclinical programs and clinical trials and its research and development programs, its ability to advance its AAV-based gene therapies into, and successfully initiate, enroll and complete, clinical trials, the potential clinical utility of its product candidates, its ability to continue to develop its gene therapy platform, its ability to develop manufacturing capability for its products and successfully transition its manufacturing process including the transition of its baculovirus/Sf9 production system to Brammer and Fujifilm, its ability to perform under existing collaborations with, among others, Sanofi Genzyme and AbbVie and manufacturers Brammer and Fujifilm and to add new programs to its pipeline, its ability to enter into new partnerships or collaborations, the sufficiency of its cash resources and the regulatory pathway of, and the timing or likelihood of its regulatory filings and approvals for, any of its product candidates, are forward looking. All forward-looking statements are based on estimates and assumptions by Voyager’s management that, although Voyager believes 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 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; Voyager’s scientific approach and general development progress; Voyager’s ability to transfer technology successfully to contract development and manufacturing organizations and the ability of such organizations to manufacture at clinical and commercial scale; and the availability or commercial potential of Voyager’s product candidates. These statements are also subject to a number of material risks and uncertainties that are described in Voyager’s most recent 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. Any forward-looking statement speaks only as of the date on which it was made. Voyager undertakes no 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.

Investor Relations:
Matt Osborne
Vice President of Investor Relations & Corporate Communications
857-259-5353
mosborne@vygr.com

Media:
Sheryl Seapy
W2O Group
949-903-4750
sseapy@w2ogroup.com

Voyager Therapeutics, Inc.