Voyager Reports Positive Topline Data for Single Ascending Dose (SAD) Trial of Anti-Tau Antibody VY7523 and Initiates Multiple Ascending Dose (MAD) Trial in Alzheimer's Disease

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- Topline SAD data from healthy volunteers demonstrate safety, tolerability, and dose-proportional pharmacokinetics, supporting potentially best-in-class profile -

- MAD study initiated in patients with early Alzheimer's disease; initial tau PET imaging data expected in H2 2026 -

LEXINGTON, Mass., March 03, 2025 (GLOBE NEWSWIRE) -- Voyager Therapeutics, Inc. (Nasdaq: VYGR), a biotechnology company dedicated to advancing neurogenetic medicines, today announced positive topline data from the Company's single ascending dose (SAD) trial of VY7523, an investigational anti-tau antibody developed to selectively inhibit the spread of pathological tau in Alzheimer's disease (AD). In the SAD trial, data on VY7523 delivered intravenously demonstrated safety, tolerability, and dose-proportional pharmacokinetics (PK). Voyager has initiated a multiple ascending dose (MAD) trial of VY7523 in patients with early AD, which is expected to generate initial tau positron emission tomography (PET) imaging data in the second half of 2026.

"We continue to view tau as the most exciting target in Alzheimer's disease, which is why we are advancing two tau-targeting approaches, our anti-tau antibody and our tau silencing gene therapy," said Toby Ferguson, M.D., Ph.D., Chief Medical Officer of Voyager Therapeutics. "For the antibody approach, we believe VY7523 could be best-in-class due to the emerging PK data and previous preclinical data showing 70% reduction in tau spread, as well as its specificity for pathological tau and for a unique C-terminal epitope. We look forward to third-party data later this year and early next year, which could continue to build excitement around tau ahead of our VY7523 tau PET data."

The SAD study was a randomized, double-blind, placebo-controlled trial to evaluate the safety, tolerability, and pharmacokinetics of single intravenous (IV) doses of VY7523 in 48 healthy volunteers. VY7523 was well tolerated across all six ascending dose cohorts, meeting the primary objective of the trial, with no serious adverse events (SAEs), severe adverse events, or infusion reactions reported. Secondary objectives of the trial were also met. Serum concentrations increased in a dose-proportionate manner, and the cerebrospinal fluid (CSF)-to-serum ratio was 0.3%, consistent with other monoclonal antibodies approved for the treatment of AD. Voyager expects to present additional data from the SAD study at an upcoming scientific conference.

The MAD study is a randomized, double-blind, placebo-controlled trial to evaluate VY7523 in 52 patients with early AD (mild cognitive impairment due to AD or mild AD). The primary endpoint is safety and tolerability. Key secondary endpoints include the ability of VY7523 to prevent the spread of pathologic tau, as measured by tau PET imaging. Initial tau PET imaging data are expected in the second half of 2026. Additional secondary endpoints include immunogenicity and pharmacokinetic parameters.

About VY7523
VY7523 is an IV-administered, recombinant, humanized IgG4 monoclonal antibody developed to inhibit the spread of pathological tau, which is closely correlated with disease progression and cognitive decline in Alzheimer's disease. VY7523 is selective for pathological tau and targets a specific C-terminal epitope of tau. In preclinical in vivo studies, the murine version of VY7523 inhibited seeding and spread of pathological tau by approximately 70%. In a single ascending dose study in healthy volunteers, data on VY7523 demonstrated safety, tolerability, and dose-proportional pharmacokinetics. Voyager is currently assessing VY7523 in a multiple ascending dose trial in patients with early Alzheimer's disease and expects initial tau PET imaging data in the second half of 2026.

About Alzheimer's Disease
Alzheimer's disease is a progressive neurodegenerative disease estimated to affect 7 million people in the U.S.[i] and up to 416 million people globally[ii]. The disease causes memory loss and may escalate to decreased independence, communication challenges, behavioral disorders such as paranoia and anxiety, and lack of physical control[iii]. In 2023, the total cost of caring for people living with Alzheimer's and other dementias in the U.S. was estimated at $345 billion[iv].

About Voyager Therapeutics
Voyager Therapeutics, Inc. (Nasdaq: VYGR) is a biotechnology company dedicated to leveraging the power of human genetics to modify the course of – and ultimately cure – neurological diseases. Our pipeline includes programs for Alzheimer's disease, amyotrophic lateral sclerosis (ALS), Parkinson's disease, and multiple other diseases of the central nervous system. Many of our programs are derived from our TRACER™ AAV capsid discovery platform, which we have used to generate novel capsids and identify associated receptors to potentially enable high brain penetration with genetic medicines following intravenous dosing. Some of our programs are wholly owned, and some are advancing with partners including Alexion, AstraZeneca Rare Disease; Novartis Pharma AG; and Neurocrine Biosciences, Inc. For more information, visit www.voyagertherapeutics.com.

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 "expect," "potential," "believe," "could," or "continue," and other similar expressions are intended to identify forward-looking statements.

For example, all statements Voyager makes regarding Voyager's ability to advance its tau antibody program, including expectations for Voyager's achievement of clinical development milestones for VY7523, such as clinical trial enrollment and the generation of clinical data; the commercial potential for VY7523; Voyager's expectations for the presentation of additional data from the SAD trial at a future scientific conference; and the potential for third-party clinical data to inform third-party interest in tau-targeting product candidates or Voyager's clinical development plans 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 and 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 expectations and decisions of regulatory authorities; the timing, initiation, conduct and outcomes of Voyager's preclinical and clinical studies; the availability of data from clinical trials; the availability or commercial potential of product candidates under collaborations; the success of Voyager's product candidates; the willingness and ability of Voyager's collaboration partners to meet obligations under collaboration agreements with Voyager; the continued development of Voyager's technology platforms, including Voyager's TRACER platform and its antibody screening technology; Voyager's scientific approach and program development progress, and the restricted supply of critical research components; the development by third parties of capsid identification platforms that may be competitive to Voyager's TRACER capsid discovery platform; Voyager's ability to create and protect intellectual property rights associated with the TRACER capsid discovery platform, the capsids identified by the platform, and development candidates for Voyager's pipeline programs; the possibility or the timing of Voyager's receipt of program reimbursement, development or commercialization milestones, option exercise, and other payments under Voyager's existing licensing or collaboration agreements; the ability of Voyager to negotiate and complete licensing or collaboration agreements with other parties on terms acceptable to Voyager and the third parties; the success of programs controlled by third-party collaboration partners in which Voyager retains a financial interest; the ability to attract and retain talented directors, employees, and contractors; and the sufficiency of Voyager's cash resources to fund its operations and pursue its corporate objectives.

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. 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.