Viage Therapeutics announces data from a Phase 1 study with DGX-001, a first-in-class oral neurotherapeutic targeting cognitive impairment in patients with Alzheimer's Disease and Parkinson's Disease

- *DGX-001 demonstrates changes in brain activity as measured by quantitative electroencephalography (qEEG), supporting a mechanism of action based on AVPR1A-dependent modulation of the gut-brain axis*

- *Company to initiate a Phase 2 proof-of-concept development program initially targeting mild cognitive impairment due to Alzheimer's Disease and Parkinson's Disease*

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Viage Therapeutics (Viage), a neuroscience company based on a platform of novel neurotherapeutics, today announced positive findings from its Phase 1 study of DGX-001, a first-in class oral therapeutic targeting the AVPR1A receptor in the gut. DGX-001 demonstrated both a favorable safety profile and proof of concept data relating to its mechanism of action (MoA), which modulates the vagus nerve via specific receptor interactions on enteroendocrine cells in the gut, with no systemic exposure of the drug and no need to penetrate the blood brain barrier. The MoA is supported by the observation of brain activity changes, as measured by qEEG, in the subjects dosed with DGX-001. These results support the initiation of a Phase 2 development program targeting mild cognitive impairment in multiple indications including Alzheimer's Disease (AD), and Parkinson's Disease (PD).

The Phase 1 study was a randomized, double-blind, placebo-controlled, safety, tolerability and pharmacokinetic study of single ascending and multiple ascending doses (MAD) of DGX-001 in 68 healthy volunteers. Subjects who received the highest dose in the MAD cohort also underwent a stress exposure resilience panel, which is based on a sleep-deprivation model believed to mimic cognitive impairment in patients with neurodegenerative diseases (like AD and PD).

The key findings from the Phase 1 study demonstrate that DGX-001 has a favorable safety profile and is well-tolerated. Following oral dosing, DGX-001 is not systemically detectable,

because it's gut-acting and gut-restricted, which supports the advantageous safety profile, particularly compared to most approved neuro-psychiatric drugs which suffer from numerous side effects. DGX-001 showed potential signals of clinical activity, including its potential to improve cognitive and executive functions, as measured through qEEG changes. Overall, these clinical results are consistent with preclinical data also indicating DGX-001's gut-restricted mechanism of action and its efficacy in models of mood and cognitive function.

"Results from the Phase 1 study provide a compelling safety profile and support further exploration of the therapeutic potential of DGX-001 in cognitive disorders," commented Titus Plattel, President of Viage Therapeutics. "We are excited to make our first-in-class oral drug candidate available to patients as we initiate the Phase 2 clinical program and in parallel discuss steps to file an investigational new drug application with the FDA."

Viage Therapeutics, formerly known as Digestome Therapeutics, is backed by investors from the US, China and Japan. The Phase 2 program of DGX-001 will initially aim to achieve cognitive improvement across different diseases, representing a transdiagnostic study design, which may ultimately enable indications beyond neurology and psychiatry.

About Viage Therapeutics

Viage Therapeutics is a neuroscience-focused company based on a platform of novel neurotherapeutics. DGX-001, Viage's lead clinical stage candidate, represents a first-in-class oral drug candidate targeting the gut-brain axis. The proposed mechanism of action of DGX-001 is to modulate the vagus nerve through specific receptor interactions on enteroendocrine cells in the gut, resulting in a regulation of brain cell activity. Viage's pipeline is comprised of both novel neuropeptides and 2nd generation DGX-001-derived peptides and small molecules. The Company is headquartered in the San Francisco Bay Area.

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