



NEWS RELEASE

Alpha Cognition Announces the Acceptance of its US FDA Investigational New Drug Application (IND) for Lead Candidate, ALPHA-1062 for Mild to Moderate Alzheimer’s Disease

VANCOUVER, B.C., September 7, 2021. **Alpha Cognition Inc. (TSX-V: ACOG, OTCQB:ACOGF)** (“Alpha Cognition”, or the “Company”), a biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with debilitating neurodegenerative disorders, today announced that the U.S. Food and Drug Administration (“FDA”), has accepted its Investigational New Drug (IND) application for lead candidate, ALPHA-1062 for the treatment of Alzheimer’s disease to proceed to the pivotal clinical phase of the development program. The Company plans to initiate a pivotal relative bioavailability study of ALPHA-1062, a proprietary, delayed release oral tablet formulation designed to treat mild to moderate Alzheimer’s Disease. This single set of trials, if successful, will allow the company to submit an NDA for ALPHA-1062 in 2022. ALPHA-1062 is being developed as a new generation of acetylcholine esterase inhibitor (AChEI) designed to improve upon the existing standard of care by overcoming gastrointestinal side effects and tolerability limitations.

“This first IND for Alpha Cognition represents a significant milestone for us as we transition to a clinical-stage organization,” said Dr. Frederick Sancilio, President and Head of Clinical Development, of Alpha Cognition. “It is well known that acetylcholine esterase inhibitors hold significant clinical potential; however, treatment with these therapies has been limited because of challenging GI tolerability issues. We have engineered ALPHA-1062 with the goal of enhancing the desirable features of an AChEI while limiting the known liabilities.”

Site initiation activities are underway for the study. The Company anticipates that enrollment will begin in the third quarter of 2021. If the results of the pivotal studies are successful, the Company expects to submit a 505(b)(2) New Drug Application as early as Q3 2022.

The clinical studies being deployed are designed to assess the equivalence of pharmaceutical products based on their pharmacokinetic profiles as compared to an existing and approved drug. They are generally performed in healthy subjects. These studies are relatively short in duration and provide a development path that is substantially less costly and more streamlined than typical clinical development programs, which require studies demonstrating safety and efficacy. The metabolite of Alpha-1062 is an approved drug (galantamine) to treat Alzheimer’s disease, and therefore qualifies for this shortened approval pathway.

A Section 505(b)(2) NDA is a new drug application in which the applicant may rely on certain investigations of safety and effectiveness that were previously conducted by someone other than the applicant, and typically relates to an active drug substance that has previously been approved in a different form.

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