



## Linical and Alpha Cognition Announce Strategic Partnership to Position Alpha-1062 for Approval in the United States and Japan Alzheimer's Markets

**Stuart, FL (April 21, 2020)** – Linical Company Limited (Linical) and Alpha Cognition Inc. (ACI) today announced they have signed a partnering agreement whereby Linical will provide strategic consulting services and regulatory guidance for Alpha-1062, a new chemical entity aimed to penetrate the Alzheimer's disease market.

Alpha-1062 is a patented new acetyl choline esterase inhibitor (AChEI) showing a significant reduction in side effects common in all other AChEI approved therapeutics. The product is being investigated in both an oral tablet and nasal spray delivery system. In placebo controlled Phase 1 and 1b human trials, the nasal formulation showed a decrease of over 90% in GI related adverse events compared to an approved AChEI at similar dose levels (Razadyne®). Parallel development programs are ongoing with targeted approval in the United States in late 2022 or early 2023 with a subsequent approval in Japan. Regulatory guidance provided by the US FDA indicate that pivotal clinical trials can be initiated in late 2020. Similar meetings with Japan's PDMA were held earlier in 2020 and indicated a similar timeline.

Linical, a mid-size contract research organization (CRO) working in CNS trials across the globe, will provide services to include: regulatory consulting, clinical trial support, post-marketing pharmacovigilance, medical information and safety support, as well as assisting with ACI's post-marketing phase IV programs. This development program will focus on the US and Japanese markets.

ACI's CEO, Ken Cawkell, commented that, "We selected Linical to be our drug development partner for this program because of their strong footprint in Japan and the US, as well as their robust clinical trials program." He went on to say, "I was impressed with the organization's capabilities in CNS clinical research and their attentiveness to our needs."

If proven effective in Alzheimer's, the enhanced delivery technology seen in Alpha-1062 could be helpful to other therapeutic areas such as Huntington's disease and schizophrenia.

"Alpha Cognition's program marks an exciting milestone in the field of Alzheimer's research. Alpha-1062 is poised to fill the need for a more effective drug with less side effects in Alzheimer's patients," said Vita Lanoce, CEO of Linical Accelerance America. "We look forward to working with Alpha Cognition on their complete development program in the US and Japan, and we see the potential of this therapy in applications beyond Alzheimer's disease."

### **About Alpha Cognition Inc.**

Alpha Cognition Inc. (ACI) is engaged in neurological disease research and has developed programs in Alzheimer's disease and amyotrophic lateral sclerosis (ALS). For additional information about ACI's research programs, visit: <http://www.alphacognition.com>.

- Alpha-1062 is a patented new chemical entity that has shown efficacy in preclinical and recently completed human clinical trials. It is being developed as a new generation of acetylcholine esterase inhibitor (AChEI) with minimal gastro-intestinal side effects and new routes of

administration. Alpha-1062 is differentiated from donepezil and rivastigmine in that it appears to also sensitize neuronal nicotinic receptors, most notably the alpha-7 subtype, which may have a positive effect on the disease. The drug is entering pivotal clinical trials later this year.

- Alpha-602 (Progranulin) is a natural protein that is expressed in several cell types in the Central Nervous System and in peripheral tissues. Alpha-602 regulates cell survival and certain inflammatory processes. The protein plays a major role in regulating lysosomal function and microglial responses. Its use in the treatment of ALS has been patented by ACI and is being investigated in preclinical models.

### **About Linical**

[Linical](#) is a market-leading, public, mid-sized CRO with a significant footprint across North America, Europe and Asia-Pacific. Linical is a global, full-service drug development partner, uniquely capable of conducting large-scale, multinational studies, while delivering personalized, hands-on service. Our areas of expertise include Phase I-IV oncology, vaccine, infectious disease, CNS and general medicine trials. We leverage regulatory consulting service, operational knowledge and patient recruitment/retention strategies to support clients in successful clinical trials.

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