



## **Alpha Cognition Inc. Receives FDA/PMDA Regulatory Guidance for Alpha-1062 Alzheimer's Therapy**

**Vancouver, BC (Canada) April 30, 2020** –Alpha Cognition Inc. (ACI) today announced that in a pre-Investigational New Drug (Pre-IND) meeting, the U.S. Food and Drug Administration (USFDA) agreed upon a clinical and regulatory pathway for the approval of Alpha-1062, a patented new chemical entity, to treat Alzheimer's disease. The FDA has suggested that a single pivotal trial, scheduled for mid 2021, may be sufficient to obtain marketing approval. ACI also met with Japan's Pharmaceutical and Medical Devices Agency (PMDA) earlier this year, who also agreed to consider a similar pathway for approval in Japan.

This follows an earlier press release announcing ACI's partnership with Linical, a Japanese based contract research organization who will provide regulatory consulting and strategic development services, including post-marketing studies, for Alpha-1062 in Japan.

ACI's Director of Regulatory Affairs, Mrs. Colleen Johns, commented that, "We are pleased with the responses we received from the FDA and the PMDA " She went on to say, "With the confirmation from the FDA that our suggested pathway is acceptable, we are well-positioned to progress the program quickly and efficiently to approval."

Alpha-1062 is being developed in both an oral tablet and nasal spray format. Clinical trials have demonstrated that, the intranasal formulation showed a decrease of over 90% in GI related adverse events compared to an approved AChEI (Razadyne®) at similar dose levels.

For additional information about the Company and its research programs, visit the Company's website at <http://www.alphacognition.com>.

**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).

- 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 acetylcholine esterase inhibitor (AChEI) with minimal gastrointestinal side effects and new routes of administration. Alpha-1062's active metabolites are differentiated from donepezil and rivastigmine in that they may sensitize neuronal nicotinic receptors, most notably the alpha-7 subtype, which may have a positive effect on the disease.
- 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.

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