IntraBio Inc is pleased to announce that *The New England Journal of Medicine* (NEJM) has published a Science Behind the Study Expert Perspective Editorial: N-Acetyl-l-Leucine and Neurodegenerative Disease.

The Editorial reports on the broad potential of N-acetyl-L-leucine (IB1001) as a treatment of neurodegenerative diseases and further describes the science behind the Phase III, pivotal study (IB1001-301) with IB1001 for the treatment of Niemann–Pick disease type C (NPC). The findings from the randomized, placebo-controlled IB1001-301 trial were also recently published in *The New England Journal of Medicine:* Trial of N-Acetyl-l-Leucine in Niemann–Pick Disease Type C.

In the trial, B1001 showed a statistically significant improvement in neurological signs and symptoms, functioning, and quality of life in pediatric and adult NPC patients with IB1001 versus placebo. The trial met its primary and secondary endpoints and showed a very favorable safety profile with no serious adverse reactions. A short Quick Take, an animated two-minute video, summarizing the highlights and key findings from the research article, is also available on **NEJM.org**

The Expert Perspective Editorial recognizes the significant potential of IB1001 for the treatment of various neurodegenerative disorders, including all neurodegenerative lysosomal storage disorders, heritable cerebellar ataxias, and common disorders like traumatic brain injury.

IntraBio has filed a New Drug Application (NDA) with IB1001 for the treatment of NPC with the US Food and Drug Administration (FDA) in January 2024. The FDA has a 60-day filing review period to determine whether the NDA is complete and accepted for review. IntraBio intends to submit its Marketing Authorization Application to the European Medicines Agency in Q2 2024. IntraBio remains dedicated to making IB1001 available to patients and families as quickly as possible to help meet the NPC community's urgent unmet medical needs.