

IntraBio Ltd. is pleased to share that IB1001-301 has enrolled over 70% of the target number of patients in the second month of recruitment. **Recruitment is expected to be completed by December 2022.**

This Phase III pivotal trial with N-acetyl-L-leucine (IB1001) will enroll a total of approximately 52 patients with Niemann-Pick disease Type C (NPC) across all international sites. Recruitment has been extremely competitive and it is not planned to screen patients past December 2022.

To ensure all patients have the opportunity to participate, interested patients are encouraged to contact their nearest study center as soon as possible to schedule a screening visit before enrollment is complete.

In the United States, the Mayo Clinic is active and recruiting:

The Mayo Clinic

Principal Investigator: Anthony Fine, MD

Contact: Bridget Neja, Clinical Research Coordinator

Email: Neja.bridget@mayo.edu

Tel: +1 (507) 538-4107

IB1001 OVERVIEW

IB1001-301 is a multinational, randomized, placebo-controlled, double-blinded, crossover Phase III study. Patients will receive treatment with both IB1001 orally-administered sachet) and a matching Placebo in two, 12-week treatment periods. Patients who complete the study will have the option to participate in an open-label extension phase, where patients will receive treatment with IB1001 for a minimum of 1-year.

Patients aged 4 years + may be eligible for recruitment at all trial sites. Patients are required to have neurological symptoms and cannot be using any other investigational agent (including investigational drugs in expanded access programs). Patients are permitted to use a stable dose of miglustat.

For the complete enrolment criteria, as well as details regarding the study assessments, multinational clinical trial sites, etc., please visit ClinicalTrials.Gov ([NCT05163288](https://clinicaltrials.gov/ct2/show/study/NCT05163288)).

If you have any additional questions on the study/recruitment, please contact:

Taylor Fields

Chief Product Development Officer & Senior Vice-President, IntraBio

Email: tfields@intrabio.com