Dear NNPDF and NPC Families,

IntraBio Inc. is pleased to share that the New Drug Application (NDA) for N-acetyl-L-leucine (IB1001) for the treatment of Niemann-Pick disease type C (NPC) was submitted to 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.

With the achievement of its first NDA submission, IntraBio is one step closer to its ultimate goal of getting IB1001 approved to help meet the NPC community's urgent unmet medical needs. IntraBio thanks the investigators, clinical trial teams, colleagues, and most importantly, members of the Patient Advocacy Community, and the NPC patients and families whose contributions and support throughout the development program have been instrumental in achieving this important milestone towards making an approved treatment available for NPC.

Best,
Taylor Fields
Chief Development Officer & President, Product Development at IntraBio Inc.