



OXFORD, UK // March 25, 2020 / IntraBio Inc., a late-stage biopharmaceutical company, today announced that the US Food and Drug Administration (FDA) has granted Fast Track designation to its lead compound (IB1001) for the treatment of Niemann-Pick disease Type C (NPC).

IB1001 (N-acetyl-L-leucine) is currently being investigated for the symptomatic, and disease-modifying, neuroprotective treatment of NPC in a multinational clinical trial (IB1001-201). In addition to the Fast Track Designation, IB1001 has previously received Orphan Drug Designations in the US (FDA) and EU (European Commission), and granted a Rare Pediatric Disease Designation in the US (FDA) for the treatment of NPC.

“The FDA’s decision to grant Fast Track designation for IB1001 is an important step in bringing this promising treatment to patients as quickly as possible,” said Taylor Fields, Senior Vice-President, IntraBio. “We look forward to working closely with the FDA to accelerate the development of IB1001 and help address the NPC community’s extremely high unmet medical need.”

The FDA’s Fast Track program facilitates the development and expedites the review of new drugs for serious, life threatening conditions like NPC. The Fast Track designation allows IB1001 to obtain potential earlier drug approval for faster access by patients, as well as rolling review and priority review.

NPC is a rare, debilitating, inherited lysosomal storage disorder that predominately affects pediatric patients. The disease begins in early childhood and is chronic and progressive. NPC severely impacts quality of life. The average age of death for NPC patients is approximately 10 years, with half of the patients dying before the age of 12.5 years.

In addition to the Clinical Study with IB1001 for NPC, IntraBio is running parallel multinational clinical trials with IB1001 for the treatment of GM2 Gangliosidosis (Tay-Sachs and Sandhoff disease; IB1001-202), and treatment of Ataxia-Telangiectasia (A-T; IB1001-203). IntraBio has also received Fast Track designation for IB1001 for GM2 Gangliosidosis.

About IntraBio

IntraBio Inc. is a biopharmaceutical company with a late-stage drug pipeline including novel treatments for common and rare neurodegenerative diseases. IntraBio's platform results from decades of research and investment at premier universities and institutions worldwide. Its clinical programs leverage the expertise in lysosomal function and intracellular calcium signaling of its scientific founders from the University of Oxford and the University of Munich.

IntraBio's management team and consultants have vast commercial experience and a successful track record of drug development in the USA and Europe. Together, IntraBio's team translates innovative scientific research in the fields of lysosomal biology, autophagy, and neurology into novel drugs for a broad spectrum of genetic and neurodegenerative diseases so to significantly improve the lives of patients and their families.

IntraBio Inc. is a US corporation with its principal laboratories and offices in Oxford, United Kingdom.

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