

IntraBio Clinical Trial Authorization Application Approved by the MHRA for the Treatment of Niemann-Pick Disease type C (NPC)

OXFORD, UK, March 11, 2019-- IntraBio Inc., a late-stage biopharmaceutical company, today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) has approved its Clinical Trial Authorisation (CTA) Application for Clinical Trial **IB1001-201** with its lead compound (IB1001) for the treatment of Niemann-Pick disease Type C (NPC).

The CTA approval of IB1001-201 allows IntraBio to proceed with the trial at UK clinical sites. The trial has been recently approved by the US Food and Drug Administration (FDA) to proceed in the United States. In addition to these centers, IntraBio intends to commence the study in Germany, Slovakia, and Spain.

“The CTA application approval represents another important milestone for our clinical program,” said IntraBio Chairman Mallory Factor. “We are looking forward to enrolling our first patient and to continuing to develop IB1001 as a potentially transformative treatment for this and other devastating diseases.”

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 in nature, and 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 Clinical Study IB1001-201, IntraBio has applied for multinational clinical trials involving IB1001 for the treatment of GM2 Gangliosidosis (Tay-Sachs and Sandhoff disease) and Ataxia-Telangiectasia (A-T). Enrollment in all three studies is expected to begin in Q2 2019.

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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