IntraBio Investigational New Drug Application Approved by the FDA for the Treatment of Niemann-Pick Disease Type C

OXFORD, UK, February 13, 2019-- IntraBio Inc., a late-stage biopharmaceutical company, today announced that the US Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) Application for Clinical Trial **IB1001-201** with its lead compound (IB1001) for the treatment of Niemann-Pick disease Type C (NPC).

The IND approval of IB1001-201 allows IntraBio to move forward with the trial at U.S. clinical sites. In addition to the U.S. centers, IntraBio intends to commence the study in European countries, including the United Kingdom, Germany, Slovakia, and Spain.

“IntraBio is grateful to the Neurologists and multinational NPC patient organizations who have helped us design this unique clinical trial to be considerate of the seriousness of NPC, and which we believe is best able to demonstrate a clear, meaningful effect of treatment with IB1001," said IntraBio’s Senior Vice-President Taylor Fields. “We look forward to continue working with the NPC community and FDA to ensure the timely development of IB1001 as a new therapeutic option for patients suffering from this devastating disease.”

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 the United States, there are no approved therapies for the treatment of NPC, and therefore an extremely high unmet medical need.

In addition to Clinical Study IB1001-201, IntraBio has received approval from the FDA for its IND Application for Clinical Trial IB1001-202 with IB1001 for the treatment of GM2 Gangliosidosis (Tay-Sachs and Sandhoff Disease), and applied for an additional multinational clinical trial involving IB1001 for the treatment of 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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