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NST doses first patient in Phase 2b clinical study of icosabutate in NASH ('ICONA')

Naarden, The Netherlands, 25 September 2019 – NorthSea Therapeutics B.V., ('NST') a Dutch biotech company developing novel and innovative strategies for the treatment of NASH (Non-alcoholic Steatohepatitis) and other metabolic, inflammatory and fibrotic diseases, today announces dosing of the first patient with icosabutate in a phase 2b dose ranging study ('ICONA').

The ICONA study (**ICO**sabutate in **NA**SH) aims to randomise 264 patients to one of three different treatment groups; placebo, icosabutate 300mg and icosabutate 600mg with a treatment period of 52 weeks. The study's primary endpoint is the resolution of NASH without worsening of fibrosis, based on changes in liver biopsy parameters from baseline to 52 weeks. Full details are available on Clinicaltrials.gov - NCT04052516. The study is expected to run until 2H 2021. An interim analysis of secondary endpoints from the first 90 patients treated for 16 weeks is planned for mid 2020 and will include safety and selected efficacy parameters. The ICONA study is being conducted at approximately 30 sites in the USA.

Icosabutate, NST's lead product, is a structurally designed fatty acid that regulates pivotal pathways involved in hepatic lipids, inflammation and fibrosis.

Rob de Ree, NST's CEO, commented: "Dosing the first patient is a pivotal milestone for the Company in our endeavour to develop a novel strategy for the treatment of NASH. I am very pleased with our productive collaboration with Dr. Stephen Harrison, MD in executing our clinical development plan for icosabutate".

Dr. Stephen Harrison, MD, Principal Investigator, added: "ICONA is an important dose ranging phase 2b study in NASH, exploring a novel, broad mechanism of action targeting the three main manifestations of NASH, namely hepatic fat, inflammation and fibrosis. It is exciting to see the study start with this first randomisation, and we expect to see swift enrolment into the ICONA study".

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Notes to Editors

About NorthSea Therapeutics

NorthSea Therapeutics B.V.(NST) is a Dutch biotech company focused on developing structurally engineered fatty acids ('SEFAs') for the treatment of inflammatory, metabolic and liver diseases. NST licensed the rights to its lead compound icosabutate and a library of discovery- and pre-clinical-stage SEFAs from Pronova BioPharma Norge AS, who developed Omacor®, a blockbuster cardiovascular drug. Icosabutate has been found safe and effective in two prior phase 2 clinical studies for treatment of hypertriglyceridemia and is currently in clinical development for NASH; a phase 2b study was commenced in July 2019 (ICONA) to study the efficacy of icosabutate in NASH. NST is a Dutch company, backed by Forbion, Novo Seeds, BGV and NSV with additional sites in the UK and Norway.

www.northseatherapeutics.com

About NASH

NASH is liver inflammation and damage caused by a buildup of fat in the liver. It is the advanced stage of a group of conditions called nonalcoholic fatty liver disease (NAFLD), which start with fatty liver and insulin resistance. Although a similar condition can occur in people who abuse alcohol, NASH occurs in those who drink little to no alcohol. It is frequently associated with insulin resistance, dyslipidemia and elevated BMI. An estimated 15-30% of the population suffers from NAFLD and 10-15% thereof may advance to NASH representing ~ 15-30 million patients in the six major markets. Further disease progression leads to fibrosis and cirrhosis with high risk for liver failure, hepatocellular cancer and need for liver transplantation.