NorthSea Therapeutics Receives FDA Rare Pediatric Disease Designation for SEFA-6179 for the Treatment of Intestinal Failure-Associated Liver Disease

- RPD designation underscores critical need for novel therapies to address IFALD

Amsterdam, The Netherlands, October 17 — NorthSea Therapeutics B.V. (NST), a biotech company developing novel and innovative strategies for the treatment of non-alcoholic steatohepatitis (NASH) and other metabolic diseases, today announced that one of its novel Structural Engineered Fatty Acids (SEFAs), SEFA-6179, has been granted Rare Pediatric Disease (RPD) Designation by the United States Food and Drug Administration (FDA) for the treatment of Intestinal Failure-Associated Liver Disease (IFALD).

SEFA-6179 is a novel, oral, fully synthetic medium chain fatty acid analog for the treatment of IFALD. The molecule has been shown to be well tolerated in a Phase 1 study in healthy volunteers.

IFALD, also known as Parental Nutrition-Associated Liver Disease (PNALD), is an orphan liver disease which is a frequent consequence of total parenteral nutrition, or TPN, a life-saving therapy for individuals with intestinal failure caused by insufficient bowel-length or function. No approved drug therapy exists for these patients.

The granting of RPD designation for SEFA-6179 underscores the critical need for novel therapies to address IFALD in the pediatric population. There is also an unmet need in adults where prolonged Total Parenteral Nutrition (TPN) use can induce IFALD with slightly different clinical manifestations versus pediatrics. Having successfully completed Phase 1 for SEFA-6179 earlier this year, NST is currently conducting a phase 2a trial to investigate PK, safety/tolerability, as well as PD effects in IFALD patients. The clinical development plan in pediatrics is under evaluation.

Rob de Ree, NST's CEO, commented: "*Receiving RPD Designation from the FDA for SEFA-6179 highlights the urgent need to advance therapeutic options for pediatric patients facing the challenges of IFALD. We are dedicated to accelerating the development of SEFA-6179 to bring hope and potentially life-saving treatment to patients and their families*."

Professor Mark Puder, Professor of Surgery, Boston Children's Hospital, stated: "*IFALD in pediatrics is a very challenging, life-threatening condition, with limited therapies. We are eagerly awaiting new effective solutions for these vulnerable patients. I strongly believe that SEFA-6179 could be candidate for treatment in pediatrics with IFALD, based on the strong pre-clinical evidence that has been generated.*"

The RPD Designation is granted by the FDA for serious or life-threatening diseases which affect fewer than 200,000 people in the United States and in which the serious or life-threatening manifestations

primarily affect individuals less than 18 years of age. Under this program, if a New Drug application (NDA) for SEFA-6179 for the treatment of IFALD is approved by the FDA, NST may be eligible to receive a Priority Review Voucher (PRV) that can be redeemed to receive a priority review for any subsequent marketing application or may be sold or transferred to a third party. This program is intended to encourage the development of new drugs and biologics for the treatment of rare pediatric diseases.

The Company is collaborating with key stakeholders and regulatory authorities to advance this promising molecule through the development process, aiming to provide a transformative treatment for patients affected by IFALD.

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 NASH and other metabolic disorders. NST licensed the rights to its lead compound icosabutate and a library of SEFAs from Pronova BioPharma Norge AS, who developed Lovaza® (US brand, branded Omacor® in Europe), a blockbuster cardiometablic drug. Icosabutate has been found safe and well tolerated in two prior phase 2 clinical studies for treatment of hypertriglyceridemia and mixed dyslipidemia and is currently in clinical development for NASH. The icosabutate phase 2b ICONA NASH trial is scheduled to readout in the second half of 2023. Two additional SEFAs are in clinical development; SEFA-1024 completed in Q4-2022, a phase 1 study and is developed for SHTG, and SEFA-6179, completed a phase 1 study in Q4-2022, is being developed for the orphan indication IFALD, (Intestinal Failure Associated Liver Disease). NST is headquartered in the Netherlands with a presence in Norway and the US and is supported by Ysios Capital, Forbion Growth, Forbion Ventures, Novo Holdings, BGV, NSV, venBio Partners and Sofinnova investments. Find out more about us online at:
www.northseatherapeutics.com

About SEFA-6179
SEFA-6179 is a novel, oral, fully synthetic medium chain fatty acid analog for the treatment of intestinal failure-associated liver disease, or IFALD. IFALD is an orphan liver disease which is a frequent consequence of total parenteral nutrition, or TPN, a life-saving therapy for individuals with intestinal failure caused by insufficient bowel-length or function. In the Phase 1 FIH clinical trial in healthy volunteers, NST observed SEFA-6179 to be well-tolerated at doses up to 1,000 mg once daily for 14 days. All treatment-emergent adverse events, or TEAEs, were mild or moderate in severity and none were severe or serious, with the most common TEAE being headaches, which resolved on treatment. The final cohort showed signals of activity with treatment in AST, ALT, gamma-glutamyl transpeptidase, or GGT, total bilirubin and direct bilirubin reductions from baseline. NST is conducting a Phase 2a PoC clinical trial of SEFA-6179 in IFALD and expects to present topline data from this trial in 2025.

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