

## Nanoformed TargTex oncology drug candidate TTX101 receives FDA Orphan Drug Designation

Press release

**Nanoform Finland Plc** 

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Helsinki, Finland – Nanoform Finland Plc (Nasdaq Helsinki NANOFH; Nasdaq Stockholm NANOFS), an innovative nanoparticle medicine enabling company, today announced its customer TargTex S.A. has been granted Orphan Drug Designation by the FDA for its nanoformed drug candidate TTX101 to be used in patients with malignant gliomas. The orphan drug designation follows the generation of a preclinical rodent data package in which a survival advantage was shown for this nanoform-enabled medicine candidate.

The hydrogel nanoformulation developed by Nanoform enabled a 200-fold increase in drug load compared to bulk and a 5-fold increase in drug load compared to nanomilling, which did not achieve the results needed. Hence Nanoform's proprietary technology and nanoformulation expertise will enable TargTex's drug candidate TTX101 to move towards clinic.

TargTexis currently raising funds to take this innovative treatment to clinic and is planning a phase 1/2a clinical trial in recurrent glioblastoma (GBM) patients across the US and EU, in which nanoformed TTX101 is applied as adjunct to surgery after tumour excision. The Orphan Drug Designation is an important milestone for TargTex Orphan Drug Designation is granted by the FDA to a drug or biological product that is developed to prevent, diagnose, or treat a rare disease or condition that affects less than 200,000 people in the United States. The designation qualifies sponsors for among other incentives 7 years of US market exclusivity after approval.

João Seixas, CEO of TarqTex, said "We are profoundly grateful to Nanoform, its technology and partnership. The FDA Orphan Drug Designation highlights the significant need of an efficacious therapy for this patient population as well as the potential of nanoforned TTX101 to benefit such patients. Our pre-clinical data showed that nanoformed TTX101 can potentially be used as monotherapy as well as a synergistic agent in combination with other drugs such as temozolomide, to treat GBM and other aggressive central nervous system tumours. We believe that delivering our drug locally at the time of surgery will bring a major benefit to patients. The drug shows a highly promising profile, with an ideal diffusion profile in the brain, without significant local or systemic toxicity and enabling tumour eradication in preclinical models in rodents".

Christian Jones, CCO of Nanoform, commented "TarqTex is a highly valued innovative client to Nanoform. We are humbled and proud to work on this devastating disease and look forward to a successful fundraising by TargTex to provide hope for patients in need".

TargTex (www.targtex.com) is a European biotech company developing a new nanoformed hydrogel-based localized therapy for the treatment of brain tumours, with the lead candidate TTX101 for glioblastoma (GBM). GBM is the most aggressive and most common brain tumour in adults, with an average life expectancy of 16 months. About 3 in 100,000 people are diagnosed with this

disease each year and there is as of yet no efficacious treatment for this deadly disease

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## **About Nanoform**

Nanoform is an innovative nanoparticle medicine enabling company. Nanoform works together with pharma and biotech partners globally to provide hope for patients in developing new and improved medicines utilizing Nanoform's platform technologies. The company focuses on reducing clinical attrition and on enhancing drug molecules' performance through its nanoforming technologies and formulation services. Nanoform's capabilities include GMP manufacturing, and its services span the small to large molecule development space with a focus on solving key issues in drug solubility and bioavailability and on enabling novel drug delivery applications. Nanoform's shares are listed on the Premier-segment of Nasdaq First North Growth Market in Helsinki (ticker: NANOFH) and Stockholm (ticker: NANOFS). Certified Adviser: Danske Bank A/S, Finland Branch, +358 40 744 1900. For more information, please visit <a href="https://www.nanoform.com">www.nanoform.com</a>.

## Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements regarding Nanoform's strategy, business plans and focus. The words may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, any related to Nanoform's business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, competition from other companies, and other risks described in the Report of the Board of Directors and Financial Statements for the year ended December 31, 2022 as well as our other past disclosures. Nanoform cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. Nanoform disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent Nanoform's views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.