

Press release

Nanoform Finland Plc

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Nanoform Commenced Relative Bioavailability Study of Nanotechnology-Enhanced Enzalutamide

Helsinki, Finland – Nanoform Finland Plc (“Nanoform”), the medicine *performance enhancing* company, today announced it had completed the First Subject First Visit (FSFV) in a trial to evaluate the relative bioavailability of its *nanocrystalline enabled* alternative to an amorphous solid dispersion (ASD) formulation of nanoenzalutamide and Xtandi[®][1], the number one prescribed androgen receptor inhibitor^[2] first approved by the FDA in 2012 to treat prostate cancer.

The single-dose, randomized, comparative bioavailability study, which is performed by a contract research organization (CRO) in North America, compares enzalutamide 160 mg film-coated tablets (Bluepharma Farmaceutica S.A.) and Xtandi 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.). Clinical trial read-out is expected during Q1 2024.

Tablet-burden and dysphagia are well-documented challenges for prostate cancer patients, and the development of a 160mg, single tablet per day regimen enabled by Nanoform technology and formulation expertise may be preferable for patients in need of reducing their total number of daily pills.

“We are pleased to have achieved First Subject First Visit as planned. The initiation of this trial represents a key milestone as we advance the development of nanoenzalutamide in prostate cancer for patients.” said Dr. Edward Haeggström, Chief Executive Officer of Nanoform. *“We continue our discussions with specialty pharma and value-added medicine partners to ensure this advance reaches the patients that need it the most. We see significant interest in nanocrystalline alternatives for Amorphous Solid Dispersions from pharma and value-added medicine partners, for whom this platform technology offers a differentiated and improved formulation that could reduce pill burden, provide a preferred route of administration or improve patient experience, acceptance and adherence.”*

If the results are positive, Nanoform and its partners will seek one or more license and/or commercial supply agreements during 2024 and equally retain 25% share of the net-income. Nanoform and three other parties have equally funded this development program.

The nanoformed enzalutamide API was manufactured at Nanoform’s state-of-the-art GMP manufacturing facility in Helsinki using its proprietary controlled expansion of supercritical solutions (CESS[®]) technology, designed to improve bioavailability, reduce the need for polymers or excipients, improve dose loading, and provide a superior patient experience.

[1] Xtandi is a registered trademark of Astellas Pharma Inc.

[2] Source: xtandi.com

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About Nanoform

Nanoform is a medicine performance enhancing 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 www.nanoform.com.

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.