Inside information made public: Nanoform Announces Important Milestone with Promising Clinical Results for Patient-Centric Nanotechnology-Enhanced Enzalutamide

Inside information

Nanoform Finland Plc

January 26th, 2024

11:20 Finnish time / 10:20 Swedish time

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THIS PRESS RELEASE CONTAINS INFORMATION THAT NANOFORM IS OBLIGED TO MAKE PUBLIC PURSUANT TO THE EU MARKET ABUSE REGULATION. THE INFORMATION WAS SENT FOR PUBLICATION THROUGH THE AGENCY OF THE CONTACT PERSONS SET OUT BELOW, ON JANUARY 26, 2024, AT 11:20 FINNISH TIME / 10:20 SWEDISH TIME.

Helsinki, Finland – January 26, 2024 – Nanoform Finland Plc ("Nanoform"), the medicine performance-enhancing company, today announced that one of its leading nanoformulation drug products had received promising clinical results. These were from a relative bioavailability study of nanocrystalline-enabled enzalutamide (nanoenzalutamide) tablet formulation, an alternative to the amorphous solid dispersion (ASD) used in Xtandi®[1], the number one prescribed androgen receptor inhibitor[2] first approved by the FDA in 2012, and by the EMA in 2013 to treat prostate cancer.

The nanoenzalutamide tablet formulation was developed in a partnership with the ONConcept® Consortium (Bluepharma, Helm, and Welding) whereby Nanoform´s proprietary controlled expansion of supercritical solutions (CESS®) technology provides the opportunity for an improved and differentiated finished product. Tablet-burden and dysphagia are well-documented challenges for prostate cancer patients, and the development of a 160mg, single tablet per day regimen may be preferable for patients in need of reducing their total number of daily pills.

The single-dose, randomized, comparative bioavailability study, which was performed by a contract research organization (CRO) in North America and completed on January 25,

2024, compared enzalutamide 160mg filmcoated tablets (Bluepharma) and Xtandi® 4x40 mg film-coated tablets (Astellas Pharma Europe B.V.). The clinical trial demonstrated promising results. Nanoform and ONConcept® will further analyze these results prior to moving ahead to enter the phase of process validation and pivotal clinical trials.

A patent application for the nanoenzalutamide formulation has already been jointly filed by Helm and Nanoform. We aim for the product launch after the expiry of the enzalutamide substance patent in the respective territories. For the United States this patent expiry is expected in 2027, and in Europe in 2028. This unique IP position may allow the nanoenzalutamide product to enter the market prior to other generic competition based on the ASD formulation, which is currently patent protected in the US and Europe until 2033.

"We are delighted to have achieved promising results from this clinical trial, bringing closer the prospect of making the lives of prostate cancer patients around the world easier in their daily struggle managing this common disease", said Dr. Edward Haeggström, Chief Executive Officer of Nanoform. "*This program exemplifies the opportunity available to create novel and improved dosage forms of existing medicines and to ensure that those drugs in clinical development are patient-centric before they reach the market. Together with our ONConcept® Consortium partners, we look forward to executing licensing deals this year and in the future to commercialize nanoenzalutamide."*

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

[2] Source: xtandi.com

Nanoform will present the conclusions in a live webcast presentation and conference call on Friday January 26, 2024, at 14:00 Helsinki time / 13:00 Stockholm time. Following the presentation there will be a question-and-answer session. Please note that you must dial in to present questions.

The presentation will be broadcast live as a webcast available at:

http://ir.financialhearings.com/pressconf-january-2024

Teleconference dial-in numbers:

Register using the link below to receive dial-in details and a conference ID for the webinar and conference call.

http://conference.financialhearings.com/teleconference/?id=5001857

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About Nanoform

Nanoform is the medicine performance-enhancing company that leverages best-in-class innovative nanoparticle engineering technologies, expert formulation, and scalable GMP API manufacturing to enable superior medicines for patients. The company focuses on reducing clinical attrition and on enhancing drug molecules' performance through its nanoforming technologies and formulation services, from pre-formulation to commercial scale. Nanoform will help improve bioavailability and drug delivery profiles, drive differentiation, patient adherence and extend the lifecycle potential of products. 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.

About ONConcept® Consortium

The three independent and certified European pharmaceutical companies – Bluepharma, Helm and Welding – joined forces in 2019 after identifying a significant opportunity for a leading partnership that can develop and manufacture complex, differentiated and highly potent products for licensing to pharmaceutical companies operating in markets around the world. ONConcept® consortium develops a portfolio of more than 15 molecules and makes them available for licensing and distribution by pharmaceutical companies around the world. The consortium is based on a profound international network and global experience in value-added products, in-house scientific-, IP-, regulatory-, and commercial expertise to be in the position to offer services covering the entire value chain according to customer needs.

Bluepharma (Portugal) operates as a contract development and manufacturing organization and has in-house all the capabilities needed to develop a medicine from scratch and, in the period before the formation of ONConcept®, began applying them to the development of complex products. Bluepharma has global regulatory approvals and experience filing submissions with authorities around the world.

Helm AG (Germany) has a strong track record of collaborating with international partners to apply its scientific, IP, regulatory and quality expertise to the development of generic and differentiated pharmaceuticals. The work has turned Helm into an experienced coordinator of different stakeholders and an expert in handling active pharmaceutical ingredients.

WELDING (Germany) has built an excellent reputation for leading projects from start to finish. Since its establishment in 1955, WELDING has been serving as a trusted global partner to companies worldwide. We distribute raw materials and offer a wide range of ready-to-use drug formulations to the healthcare community.

Nanoform 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.