NANOFORM STARTS PIVOTAL HUMAN BIOEQUIVALENCE STUDIES OF NANOENZALUTAMIDE

Nanoform Finland Plc | Press Release | June 12, 2025 at 08:10:00 EEST

HELSINKI, FINLAND, June 12, 2025 - Nanoform Finland Plc, the medicine performance-enhancing company, today announced that it had started pivotal relative bioequivalence studies of Nanoenzalutamide, the nanocrystalline-enabled enzalutamide tablet formulation, a potential alternative to the amorphous solid dispersion (ASD) used in XTANDI® (enzalutamide) [1], the number one prescribed androgen receptor inhibitor [2] approved to treat prostate cancer.

The studies are being conducted in fed and fasted healthy volunteers, for both U.S. and Europe. The purpose is to achieve bioequivalence for a single nanoformed 160 mg tablet dose with four XTANDI® 40 mg film-coated tablets. With the clinical results we are on track to support product launch post expiry of the enzalutamide substance patent in the respective territories.

The nanoenzalutamide tablet formulation was developed in a partnership with the ONConcept® Consortium (Bluepharma, Helm, Welding). Tablet-burden and dysphagia are well-documented challenges for prostate cancer patients, and the development of a nanoformed once-per-day regimen may be preferable for patients in need of reducing their daily pill burden.

"We commenced this bioequivalence study as planned and our commercialization partners are excited about our CESS® technology, the IP advantages, the patient, sustainability & cost benefits and hence see significant commercial value in Nanoform's technologies" said Prof. Edward Haeggström, CEO of Nanoform.

The first license and supply agreement (LSA) has now been signed (Germany), while LSAs for several other key markets (e.g. US, Japan, France) are expected to be signed in the coming months. The total value the Nanoenzalutamide project could bring to Nanoform and its ONConcept® partners is EUR 10m+ in potential development milestones up until launch, EUR 25m+ in potential commercial milestones and significant profit share after launch.

Nanoform continues to advance its other small and large molecule product kernels and customer projects to clinic.

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

[2] Source: xtandi.com

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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: Carnegie Investment Bank AB (publ), +46 8-588 68 570. 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, 2024 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.]

Attachments

Nanoform starts Pivotal Human Bioequivalence Studies of Nanoenzalutamide