



FIMEA renews Nanoform's GMP license and Nanoform starts clinical API manufacturing of a blockbuster medicine candidate

Press release

Nanoform Finland Plc

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Helsinki, Finland – Nanoform Finland Plc, an innovative nanoparticle medicine enabling company, are delighted to announce that FIMEA (Finnish Medicines Agency) has completed another successful general good manufacturing practices (GMP) inspection of Nanoform. During the inspection on March 28th, 2023, FIMEA fully reviewed Nanoform for compliance with its processes and adherence to GMP for the manufacture of multiple clinical active pharmaceutical ingredients (APIs). Nanoform received no critical or major observations during this inspection, which is a testimony to the importance Nanoform places on quality in everything it does and received by FIMEA a renewed licence May 8th, 2023.

As previously communicated, following this renewed licence Nanoform has now commenced GMP manufacture for nanoforming of a currently marketed blockbuster drug for a clinical trial planned in Q4 2023. Nanoform has also been audited by an independent European GMP auditor for this project and again received no critical or major observations.

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About FIMEA

The Finnish Medicines Agency Fimea is the national competent authority for regulating pharmaceuticals. As a central administrative agency operating under the Ministry of Social Affairs and Health it promotes the health and safety of the population by regulating medicinal, medical devices, blood and tissue products, biobanks and by developing the pharmaceuticals sector. For more information, please visit <http://www.fimea.fi/web/en>

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 <http://www.nanoform.com>

Forward-looking statements

This press release contains forward-looking statements, including, without limitation, statements regarding Nanoform's ongoing projects, 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.