Additional Positive Interim Results from Nanoform’s Clinical Study

Insider information
Nanoform Finland Plc
February 24, 2021
08:10 a.m. Finnish time / 07:10 a.m. Swedish time

Nanoform Finland Plc, an innovative nanoparticle medicine enabling company, today announced further positive interim results from its ongoing clinical study. The fast absorption data implies that small is powerful® and might offer viable alternatives to complex formulation approaches such as cyclodextrin based technologies.

Nanoform has received the second interim pharmacokinetic (PK) study results related to its Phase 1, single-centre, part crossover, open-label, partially-randomised study designed to evaluate the PK profile of piroxicam following administration of nanoformed oral immediate release (IR) piroxicam tablet and IR reference products in healthy subjects (UNICORN).

The first set of interim human data (released January 22, 2021) showed faster absorption of Nanoform’s CESS® nanoformed formulation against Felden®, the reference product, marketed by Pfizer. In the second part of the study, Nanoform evaluated the performance of the same nanoformed piroxicam tablet formulation against a β-cyclodextrin coupled piroxicam oral tablet (Brexidol®) marketed by Chiesi, a fast-absorbing formulation available on the market.

One of Nanoform’s value propositions is that CESS® nanoparticles may offer viable alternatives to complex formulations. By avoiding the use of cyclodextrin it is potentially possible to achieve increased drug loads and smaller dosage forms (e.g., tablets and capsules). This was supported by the study, where the 20 mg CESS® nanoformed oral piroxicam showed equal absorption performance when compared to a 20 mg Brexidol® tablet. In addition, the standard deviation of absorption of the nanoformed formulation was lower than that of both marketed products, which may mean less variability in the therapeutic response in patients.

The nanoformed formulation was developed to prove the clinical utility of the CESS® technology for fast acting forms of drugs. This has been addressed through this trial. As expected, the results indicate similar bioavailability to both reference products. This provides hope for quickly introducing improved versions of existing products or adding value to those already in clinical development.

This set of human data supports Nanoform’s claim that nanoparticles can enable faster dissolution rate, more rapid absorption, improve drug delivery performance, and ultimately generate patient benefit. These findings are relevant for drugs being developed where fast action is required, such areas include but are not limited to pain and inflammation, migraine, depression, cardiology, vertigo, stroke, epilepsy and erectile dysfunction; or where pill burden is an issue, such as people who have difficulty swallowing (e.g., children and elderly patients).

These interim results are based on the cohort of twelve healthy volunteers dosed in December 2020 and January 2021 at Quotient Sciences’ facilities in Nottingham, UK. Final results of the study are expected before the end of Q2 2021, as previously announced.

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The information in the press release is information that Nanoform is obliged to make public pursuant to the EU Market Abuse Regulation. The information
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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 40 562 1806. 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 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 specified in Nanoform’s prospectus published (on May 22, 2020) in connection with Nanoform’s initial public offering (the “Prospectus”) under “Risk Factors” and in our other filings or documents furnished to the Finnish Financial Supervisory Authority in connection with the Prospectus. 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.