Nanoform's final clinical results confirm value proposition to the pharma industry

Press release

Nanoform Finland Plc

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Helsinki, Finland – Nanoform Finland Plc ("**Nanoform**"), an innovative nanoparticle medicine enabling company, today announced the completion and final results of its clinical study. The primary, secondary and optional exploratory objectives of the study were all met. The results show that Nanoform's CESS® technology enabled development of a fast-acting piroxicam immediate release (IR) tablet formulation with more rapid absorption and improved drug delivery performance in comparison to a standard reference IR tablet. The study outcome confirms published interim results (Jan 22 and Feb 24) and supports the clinical utility of Nanoform's technology and its potential applicability for producing fast-acting dosage forms for poorly soluble drugs.

Nanoform has now received the final clinical study report on the pharmacokinetic (PK) study results related to its Phase 1, single-center, part crossover, open-label, partially-randomized study designed to evaluate the PK profile of piroxicam following administration of nanoformed oral IR piroxicam tablets and IR reference products in healthy subjects (UNICORN).

The primary objective of the study was to determine the PK and relative bioavailability of piroxicam following oral administration of single 20 mg nanoformed piroxicam IR tablets and reference product Felden® 20 mg tablets (Pfizer) in healthy subjects in the fasted state. The secondary objective was to provide additional safety and tolerability information for piroxicam following administration of nanoformed piroxicam tablets in healthy subjects. The additional exploratory objective was to determine the PK and relative bioavailability of piroxicam following oral administration of single 20 mg nanoformed piroxicam IR tablets and additional reference product Brexidol 20 mg tablets (Chiesi) in healthy subjects in the fasted state. Brexidol is a β-cyclodextrin coupled formulation designed for fast absorption, therefore rapid absorption for this reference product was expected *in vivo*.

The nanoformed tablets demonstrated a time of maximum plasma concentration (T_{max} = 1.75 h, ranging from 0.75 h to 4.00 h) earlier relative to both reference products: Felden (T_{max} = 2.75 h, ranging from 0.75 h to 12.00 h) and Brexidol (T_{max} = 2.25 h, ranging from 0.5 h to 8.00 h). The slightly faster absorption observed for the nanoformed piroxicam tablets compared to Brexidol shows that nanoforming can be used as an alternative or improvement to complex formulation approaches, such as those using β-cyclodextrin, with the potential for having improved performance without the need for additional excipients. Thus, nanoforming can enable simpler formulation strategies and higher drugs loads in final drug products compared to complex formulations, where high amounts of excipients are needed and in turn restrict drug content in the formulated product.

There was no significant difference in maximum plasma concentrations (C_{max}) between the tested products (nanoformed 2230 ng/ml, Felden 2230 ng/ml and Brexidol 2300 ng/ml). The nanoformed piroxicam tablets had an increased Area Under the Curve (AUC) during the first hour after dosing (AUC(0-1))(1150 ng*h/ml), showing 33% improvement compared to Felden (863 ng*h/ml) and was very similar to Brexidol (1180 ng*h/ml). These results demonstrate the fast absorption of piroxicam from nanoformed tablets. Overall plasma exposure (AUC(0-last)) of nanoformed piroxicam (83600 ng*h/ml)

was similar to that of Felden (85900 ng*h/ml) and was slightly lower than that of Brexidol (92000 ng*h/ml). As the literature indicates, the piroxicam fraction absorbed following oral administration is close to 100%, and thus the similarity in AUC response between the IR dosage forms tested in this study was anticipated.

Peak plasma concentration variability (coefficient of variation, CV) was observed to be lower in the nanoformed piroxicam tablets (15.6) than both reference products (Felden 18.8 and Brexidol 17.1). This may be due to a more uniform and reproducible total surface area for nanoformed piroxicam drug particles within the tablet facilitating a more uniform dissolution and subsequent absorption. Reduced concentration variability could potentially offer benefits in downstream response variation.

Nanoformed piroxicam was well tolerated, with no adverse effects reported. Some adverse effects were shown with both of the reference products.

The nanoformed formulation was developed at Nanoform to prove the clinical utility of the CESS® technology for faster acting forms of poorly soluble drugs. This was addressed and confirmed through this trial. The results indicate similar bioavailability to both reference products, and the C_{max} values show no statistically significant difference. This provides hope for quickly introducing improved versions of existing products and for adding value to those already in clinical development. The data indicates that small is powerful® and offers the industry a viable alternative to complex formulation approaches, such as β-cyclodextrin based technologies. These results pave the way for improving absorption and increasing drug load while enabling simpler formulations to maximize patient benefit.

These findings are relevant for all poorly soluble drugs, which comprise 70-90% of small molecule therapeutics in development, and specifically can add value 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).

The final results are based on the cohort of twelve healthy volunteers dosed in December 2020 and January 2021 at Quotient Sciences' facilities in Nottingham, UK.

Quotient Sciences' study report can be found at: https://nanoform.com/en/articles-videos/

Chris Roe, Senior Research Fellow at Quotient Sciences, will present the clinical study, objectives and results at CPhI Discover online event May 20, 2021, 'Overcoming Drug Development Challenges with Nanotechnology': https://exhibitors.cphi.com/pdig21/agenda.html

Nanoform will present the clinical conclusions in conjunction with Nanoform's already scheduled Q1/2021 report conference call and online presentation to analysts, investors and media May 27, 2021: https://nanoform.com/en/invitation-to-presentation-of-nanoforms-q1-2021-report-on-may-27-2021/

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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 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.