Nordic Nanovector completes enrolment into second safety cohort of follicular lymphoma patients in Archer-1 Phase 1b Betalutin®/rituximab combination trial

19.11.2020 07:02

Oslo, Norway, 19 November 2020

Nordic Nanovector ASA (OSE: NANO) announces that it enrolled the final two patients into the second safety cohort of its Phase 1 Archer-1 (LYMRIT 37-07) trial investigating safety and preliminary efficacy of Betalutin® (177Lu lilotomab satetraxetan) in combination with rituximab in 2nd-line follicular lymphoma (2L FL).

The dosing regimen in this cohort is a single administration of 15 MBq/kg Betalutin® preceded by 40mg lilotomab, followed by 375 mg/m² rituximab once per week for four weeks.

Data from this cohort is expected in H1'2021 and will be analysed alongside the data generated from the first cohort of patients receiving 10 MBq/kg Betalutin®/40mg lilotomab.

As announced in April 2020, Archer-1 is expected to be paused pending this analysis, which is expected to inform plans for the further development of Betalutin® development in 2L FL. The Company's primary focus for its resources is on the timely completion of the pivotal Phase 2b PARADIGME trial of Betalutin® in 3rd-line FL (3L FL).

Christine Wilkinson Blanc, Chief Medical Officer of Nordic Nanovector, said: "We are pleased to complete patient enrolment into the second safety cohort of Archer-1. We look forward to the results from this cohort in H1'2021, which will add to our understanding of Betalutin® use in FL patients. The data will also inform our thinking towards further development strategies for Betalutin® in broader FL populations than that being investigated in our PARADIGME trial in 3L FL."

About Archer-1

Archer-1 is a Phase 1b open-label, single-arm, multi-centre dose-escalation trial designed to assess the safety and preliminary activity of combining the CD37-targeted radioimmunoconjugate Betalutin® with the CD20-targeted immunotherapy rituximab in patients with relapsed/refractory (2L) FL who have received one or more prior therapies.

Rituximab was approved for the treatment of non-Hodgkin's lymphoma (NHL), including FL, more than 20 years ago and is the current standard of care. It is administered to patients with newly diagnosed or relapsed FL as a single agent or in combination with chemotherapy. Over time, patients may develop resistance to rituximab, thus alternative targets and new treatments are important.

For further information, please contact:

IR enquiries

Malene Brondberg, CFO

Cell: +44 7561 431 762

Email: ir@nordicnanovector.com

Media Enquiries

Mark Swallow/Frazer Hall/David Dible (Citigate Dewe Rogerson)

Tel: +44 203 926 8535

Email: nordicnanovector@citigatedewerogerson.com

About Nordic Nanovector:

Nordic Nanovector is committed to develop and deliver innovative therapies to patients to address major unmet medical needs and advance cancer care. The Company aspires to become a leader in the development of targeted therapies for haematological cancers. Nordic Nanovector's lead clinical-stage candidate is Betalutin®, a novel CD37-targeting antibody-radionuclide-conjugate designed to advance the treatment of non-Hodgkin's lymphoma (NHL). NHL is an indication with substantial unmet medical need, representing a growing market forecast to be worth nearly USD 29 billion by 2026. Nordic Nanovector retains global marketing rights to Betalutin® and intends to actively participate in the commercialisation of Betalutin® in the US and other major markets.

Further information can be found at www.nordicnanovector.com.

Forward-looking statements

This press release contains certain forward-looking statements. These statements are based on management's current expectations and are subject to uncertainty and changes in circumstances, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on Nordic Nanovector's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "targets", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. These forward-looking statements are not historic facts. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in the forward-looking statements. Factors that could cause these differences include, but are not limited to, risks associated with implementation of Nordic Nanovector's strategy, risks and uncertainties associated with the development and/or approval of Nordic Nanovector's product candidates, ongoing and future clinical trials and expected trial results, the ability to commercialise Betalutin®, technology changes and new products in Nordic Nanovector's potential market and industry, Nordic Nanovector's freedom to operate (competitors patents) in respect of the products it develops, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions, and legislative, regulatory and political factors. No assurance can be given that such expectations will prove to have been correct. Nordic Nanovector disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

This information is subject to a duty of disclosure pursuant to Sections 4-2 and 5-12 of the Securities Trading Act.