

Nordic Nanovector Publishes Data from the PARADIGME Phase 2 Clinical Trials with Betalutin® on European Clinical Trials Database

Oslo, Norway, 18 April 2023

Nordic Nanovector ASA (OSE: NANOV) ("Nordic Nanovector" or the "Company") announces that full results from its Phase 2 clinical trials of Betalutin® (¹⁷⁷Lu lilotomab satetraxetan) in resistant/refractory (R/R) indolent non-Hodgkin's lymphoma (NHL) have been published at EudraCT, the European Union Drug Regulating Authorities Clinical Trials Database (the database for all interventional clinical trials on medicinal products submitted to the National Competent Authorities (NCAs) of the European Union). The data from the Phase 1b/2a LYMRIT 37-01 and the Phase 2b PARADIGME studies can be found via this link:

[EU Clinical Trials Register](#)

As previously announced on 5 July 2022, the PARADIGME trial of Betalutin® in 3rd-line follicular lymphoma patients refractory to rituximab/anti-CD20 (3L R/R FL) was discontinued following a comprehensive review and independent data evaluation and a subsequent request for regulatory agency interaction. The data from the 109 patients enrolled in PARADIGME up until its discontinuation show:

- Overall response rate (ORR) was 38.9% and 32.1%; complete response (CR) rate was 20.8% and 14.3% in participants receiving doses of 40/15 (Betalutin® dose of 15 MBq/kg after a pre-dose of 40 mg lilotomab) and 100/20 (Betalutin® dose of 20 MBq/kg after a pre-dose of 100 mg lilotomab), respectively.
- Median duration of response (DoR) was approximately 8.5 months for the 40/15 dose and 3.4 months for the 100/20 dose. Median duration of complete response (DoCR) was 8.5 months for 40/15 and 9.2 months for 100/20. DoR and DoCR are difficult to interpret due to the small number of responders.
- Over half the participants had progressed 6 months following treatment. The median progression-free survival (PFS) was 5.9 months versus 5.8 months with 40/15 and 100/20, respectively.
- The majority of treatment emergent adverse events (TEAEs) were due to cytopenias, most notably decreases in platelets (thrombocytopenia was observed in 19 [16.8%] and platelet count decreased in 11 [9.7%] participants) and neutrophils (neutropenia in 18 [15.9%] and decreased neutrophil count in six [5.3%] participants). Anaemia and fatigue were also reported in >10% of participants.

As previously communicated in the 5 July 2022 announcement, the former Board of Directors of Nordic Nanovector took the decision to wind-down PARADIGME in a structured manner while ensuring that patients received the best possible care during this period, as the observed profile did not fully meet the objectives set out for the study. As a result, the former Board was of the opinion that the demonstrated profile was no longer sufficiently competitive to bring Betalutin® to the market in 3L R/R FL within a timeframe that made financial and commercial sense for the Company. The current board and management concurs with the decision to discontinue PARADIGME and Betalutin® development in the 3L R/R FL indication.

The Company still believes there could be a market for Betalutin® in light of its safety profile, promising efficacy in earlier lines of therapy and unique feature of being delivered as a one-time dose. However, a potential new development programme would need to be conducted in a different patient population and line of treatment and would require significant financial resources.

The Company is exploring all strategic options including potential partnerships to see if there is a possible way forward for Betalutin® in an alternative setting.

Pipeline update:

The rest of Nordic Nanovector's pipeline consists of:

1. Humalutin®: a radioimmunotherapy candidate based on a chimeric anti-CD37 antibody and the beta-emitting radionuclide lutetium-177 for NHL. The project has been on hold since 2016 and all preclinical data have been published in the following journals:

- [The European Journal of Nuclear Medicine and Molecular Imaging](#)
- [Nature Scientific Reports](#)
- [PLOS ONE](#)

2. Alpha37: an alpha-emitting radioimmunotherapy candidate based on a chimeric anti-CD37 antibody conjugated to lead-212. The project is a collaboration with partner OranoMed and has been on hold since 2021. All preclinical data has been published in:

- [PLOS ONE](#)

3. Fully humanized anti-CD37 antibodies with potential in haematological cancers and autoimmune diseases. Preclinical data were presented in two posters at ASH, both available on the Nordic Nanovector website:

- [ASH posters](#)

The project has been on hold in 2023.

4. CD37 DOTA CAR-T cell opportunity in haematological cancers is a research collaboration with the University of Pennsylvania. Data from preliminary investigations were inconclusive and the project has been put on hold.

5. Solid tumour radioimmunotherapy: a project directed at radioimmunotherapy for solid tumours, where target identification has been concluded and several interesting molecular targets for solid tumour indications have been identified. Validation of targets and testing of minimal viable products are being evaluated.

The Board continues to focus on reducing costs where necessary to enable the Company to minimise cash burn until a strategic partner can be found.

No assurances can be given as to the outcome or timing of the ongoing strategic review process. The Company will put forward any recommended proposals for resolution by shareholders in due course.

IR enquiries

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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.

Further information can be found at www.nordicnanovector.com

Forward-looking statements

This press release contains certain forward-looking statements relating to inter alia to the business and strategies, financial performance and results of the Company. Forward-looking statements concern future circumstances and results and other statements that are not historical facts. These statements are based on Nordic Nanovector's current expectations and are subject to uncertainty and changes in circumstances. Any forward-looking statements contained in this release, including assumptions, opinions and views of Nordic Nanovector or cited from third party sources, are subject to risks, uncertainties and other factors that may cause actual results and events to be materially different from those expected or implied by the forward-looking statements. Nordic Nanovector cannot provide any assurance that the assumptions underlying such forward-looking statements are free from errors nor accept any responsibility for the future accuracy of opinions expressed in this release or the actual occurrence of any forecasted developments. Nordic Nanovector disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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. 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 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.

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