NORDIC NANOVECTOR

Press releases

Nordic Nanovector completes patient enrolment into Phase 1 trial of Betalutin[®] in Diffuse Large B Cell Lymphoma

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Nordic Nanovector ASA (OSE: NANO) announces that it has completed enrolment into the LYMRIT 37-05 Phase 1 clinical trial of Betalutin® (^{177}Lu lilotomab satetraxetan) in patients with relapsed/refractory diffuse large B-cell lymphoma (R/R DLBCL) not eligible for autologous stem cell transplantation (ASCT).

Eighteen DLBCL patients were enrolled into the trial at clinical trial sites in the US and Europe and were dosed with three escalating treatment doses of Betalutin® (10MBq/kg, 15MBq/kg and 20MBq/kg). A preliminary data readout is expected in H1'2021.

As announced in April 2020, LYMRIT 37-05 will be paused pending analysis of these data, which is expected to inform plans for the further development of Betalutin® in R/R DLBCL.

Nordic Nanovector's primary focus is the timely completion of the pivotal Phase 2b PARADIGME trial of Betalutin® in 3rd-line follicular lymphoma (3L FL).

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Christine Wilkinson Blank, Chief Medical Officer of Nordic Nanovector, said: "The completion of recruitment into this dose-finding study in patients with DLBCL is an important milestone. DLBCL remains a significant indication with a large unmet medical need. The data analysis from this trial will form the basis of our considerations for the further development of Betalutin® in DLBCL and more broadly across non-Hodgkin's lymphoma."

The LYMRIT 37-05 study is a Phase 1 open-label, single-arm, dose-escalation study in DLBCL designed to determine the dose to be recommended for further studies in DLBCL and assess the safety, tolerability, pharmacokinetic profile and preliminary anti-tumour activity of a single administration of Betalutin®. More information on this study can be found at www.clinicaltrials.gov (http://www.clinicaltrials.gov) (NCT02658968).

DLBCL is an aggressive form of non-Hodgkin's Lymphoma (NHL) that accounts for 30% of all NHL cases[1,2]. The number of diagnosed incident cases of DLBCL in the seven major markets (US, key five European markets and Japan) was 64,172 in 2018 and is expected to grow to 74,927 in 2028[3].

Approximately 40% of DLBCL patients relapse after first-line combination treatment with rituximab and chemotherapy. These patients have few therapeutic options, with high-dose chemotherapy and autologous stem cell transplant (ASCT) achieving long-term remissions in only a minority of patients[4]. Relapsed DLBCL therefore remains a serious unmet medical need.

References

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3. Non-Hodgkin's Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL), 2020, Decision Resources Group, Clarivate
4. Liu Y, Barta SK. Diffuse large B-cell lymphoma: 2019 update on diagnosis, risk stratification, and treatment. Am J Hematol. 2019 May;94(5):604-616.

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About Nordic Nanovector

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 (http://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.

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