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PRESS RELEASE from NucliThera AS:

Results from Nordic Nanovector's PARADIGME study of Betalutin in patients with follicular lymphoma have been published in the scientific journal *Pharmaceuticals*.

Summary: The manuscript findings show that Betalutin had substantial antitumour activity, was well tolerated and had a manageable adverse event profile. The PARADIGME data showed a trend towards better efficacy in patients treated with the 40/15 regimen compared with the 100/20 regimen. Patients with grade I–IIIa follicular lymphoma (FL) who had received at least two prior lines of treatment and were refractory to at least one previous regimen containing rituximab or another anti-CD20 agent were included. The study also showed that treatment efficacy was reduced in treatment-resistant patients, and that the average patient had failed as many as three lines of treatment rather than the intended two. The time to relapse following the last treatment before Betalutin was also markedly shorter in the PARADIGME study than in the phase I cohort, illustrating that the patients were “sicker” than intended.

Methods: All patients received rituximab two weeks before Betalutin to deplete circulating B cells that could otherwise bind Betalutin before it reached the tumour. Patients were randomised to receive either a pre-dose of 40 mg lilotomab and an activity dose of 15 MBq/kg Betalutin (the “40/15” regimen), or 100 mg/m² lilotomab and 20 MBq/kg Betalutin (the “100/20” regimen). A total of 109 patients were enrolled and received Betalutin, of whom 72 received the 40/15 regimen and 28 received the 100/20 regimen. An additional “special population” group of nine heavily pretreated patients received 40/12.5 (i.e. a reduced Betalutin dose) because of low platelet counts and/or a previous autologous stem cell transplant. Part C was a small expansion cohort of four patients, all treated with the 40/15 regimen, designed to collect additional pharmacokinetic data. The study was registered on ClinicalTrials.gov under study number NCT01796171.

Results: The efficacy analysis set comprised a total of 100 patients from the PARADIGME study. The overall response rates were 38.9% and 32.1%, and the complete response rates were 20.8% and 14.3% in the 40/15 and 100/20 groups, respectively. The median duration of response was 8.5 months and 3.4 months in the two groups, respectively. This shows that treatment efficacy did not improve when the Betalutin activity dose was increased with greater protection of normal tissue through increased CD37 pre-dosing in the 100/20 group. The most common grade ≥3 adverse events were haematological, i.e. decreases in blood cell counts, including neutropenia (11.5%) and thrombocytopenia (8.0%), with nadirs around weeks 5–7 and recovery by week 11.

Conclusions: A single dose of Betalutin had a mild toxicity profile and a clinically modest but relevant response rate. It represents a promising treatment option for patients who are unsuitable for more aggressive therapies with more severe adverse effects and repeated or longer courses of treatment.

The article on the PARADIGME study is available at:

<https://www.mdpi.com/1424-8247/19/2/250>

The discussion section of the article also referred to the Archer study, in which a single dose of Betalutin was combined with repeated doses of rituximab in patients who had received one prior line of treatment (i.e. as second-line treatment). Seven patients were enrolled, and all (100%) achieved a response, with five of seven achieving a complete response, indicating promising efficacy. For example, this can be compared with the recently approved combination of the bispecific antibody EPKINLY plus rituximab and lenalidomide, administered as repeated treatments and approved in November 2025 for second-line follicular lymphoma, with a response rate of 89% (<https://www.targetedonc.com/view/fda-approves-epcoritamab-based-regimen-in-follicular-lymphoma>).

About Betalutin: CD37 is an antigen that is highly expressed in B-cell malignancies and served as the target in the LYMRIT-37-01 Part A, Part B (PARADIGME) and Part C studies, using a single intravenous injection of the radioimmunoconjugate ¹⁷⁷Lu–lilotomab satetraxetan (Betalutin®). NucliThera AS, which acquired the rights to commercialise Betalutin from Thor Medical ASA in exchange for a share of any future profits, will seek a partner to finance the resumption of development and further advancement, if possible.

About NucliThera AS: NucliThera is an R&D company developing targeted, short-range radionuclides for the treatment of metastatic cancers, including lymphoma and leukaemia. High-energy alpha- and beta-emitting radionuclides are linked to targeting monoclonal antibodies or small molecules. These bind to cancer cells and kill them with minimal damage to surrounding healthy tissue.

NucliThera's research team is jointly led by Chief Scientific Officer Dr Ada Repetto-Llamazares, Chief Technology Officer Dr Roy H. Larsen and Chief Medical Officer Professor Emeritus Øyvind S. Bruland. Dr Larsen and Professor Bruland's pioneering work includes the development of Xofigo, an alpha-emitting therapy for bone metastases from prostate cancer.

Contact:

Chairman Roy H. Larsen +47 920 16 487

Chief Medical Officer Øyvind S. Bruland +47 971 74 004