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## Introductory remarks by the Chairman





### Recently, significant improvement in recruitment rate

- The operational improvements implemented during 2020 have resulted in a significant recent acceleration of the recruitment rate
  - Recruitment rate increased from approx. two to approx. five patients per month despite COVID
  - After the expected lessening of COVID restrictions plus the ongoing operational improvements, this rate could further increase to at least seven patients on average per month by late spring
- Improved recruitment rates are the results of a number of operational changes:
  - Significantly improved management of CRO and retained specialised firm to further improve recruitment
  - The conversion of PARADIGME from a two-arm to a single-arm trial simplified execution for clinicians
  - Positive safety data from the Interim Analysis allowed us to broaden our inclusion criteria
    - Patients with lower platelet counts and after bone marrow transplant increased the pool of eligible patients by 30–50%
  - Analysis of Interim data showed that number of patients required to complete PARADIGME can be reduced
- Due to the protocol amendment the total required patients was reduced to 120 and therefore an additional 47 patients are required to complete PARADIGME for regulatory submission of Betalutin®
- Reiterating target to report preliminary three-month top-line data in H2'2021





- 73 patients enrolled as of 17 February 2021 (59 enrolled as of 18 November 2020)
- 14 patients were enrolled from 18 November to 17 February (three patients from August to November 2020)
- Protocol amendments are now being implemented following approval in all 24 countries
- Final patients enrolled into second safety cohort of Archer-1 Phase 1 trial of Betalutin® plus rituximab in 2L R/R FL and into LYMRIT 37-05 Phase 1 trial of Betalutin® in patients with DLBCL
  - Preliminary data readouts expected in H1'2021
  - Both trials to be paused pending analysis of data and evaluation of plans for further development
- Results of preclinical studies demonstrating Betalutin® reverses tumour resistance to rituximab in NHL disease models published in Journal of Nuclear Medicine







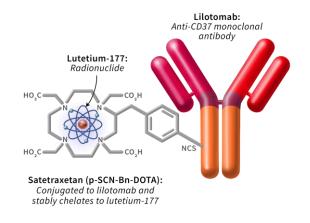




# Betalutin® has a compelling, unique and differentiated value proposition for NHL patients



## Betalutin®: A novel CD37-targeting radioimmunotherapy



- CD37 is highly expressed in B-NHL\*
- <sup>177</sup>Lu: a low energy β-emitter with a half-life of 6.7 days
- Mechanism of action:
  - Internalization and cell death
  - Crossfire effect targets cells with variable CD37 expression and poorly-vascularized tumour regions

#### **Key Benefits**

Single-dose treatment

Durable responses in elderly and heavily pre-treated NHL patients

Predictable and manageable side-effect burden

Alternative target to CD20: suitable for rituximab refractory patients



## Clinical development strategy focused on capturing significant value from Betalutin® in NHL



#### **Core Focus**

#### **PARADIGME**

#### Single-agent Betalutin® in 3L R/R FL

- Targeting 3L R/R FL as first-to-market indication
- Evaluating optimal strategy to advance into earlier lines
- Evaluating opportunity to investigate in R/R MZL based on:
  - Promising response in LYMRIT 37-01
  - Clear unmet need reflected in Fast-track (US) and Orphan Drug (EU) designations
  - Possibility to augment patient flow into PARADIGME leveraging existing infrastructure

#### Cohorts finalized and data analysis ongoing

#### Archer-1

#### Betalutin® + RTX in 2L R/R FL

- · Good initial efficacy, but recruitment was very slow
- Need to consider future positioning and optimal strategy

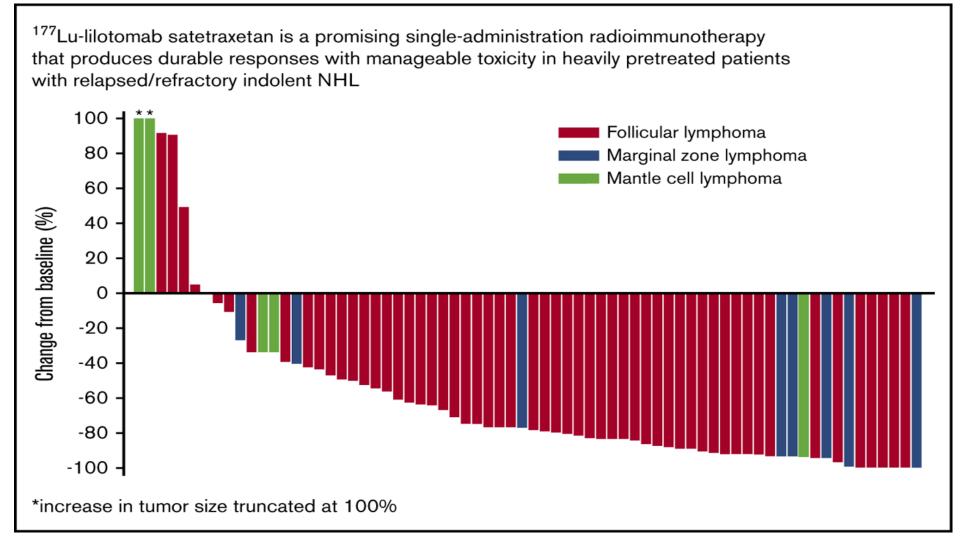
**LYMRIT 37-05** 

#### Single-agent Betalutin® in DLBCL

- · Recruitment was very slow
- DLBCL remains an important indication need to evaluate optimal development strategy
- All pre-clinical and research initiatives (Alpha37) to be paused after IND submission



# LYMRIT 37-01 – Part A: One dose of Betalutin® reduced tumour size in 90% of evaluable patients





## LYMRIT 37-01 – Part A: Highly promising efficacy in R/R FL and MZL



## Compelling response rate in FL and MZL patients from a single administration

	ORR	CR
All patients (n=74)	61%	30%
All FL patients (n=57)	65%	30%
FL with ≥2 prior therapies (n=37)	70%	32%
RTX-refractory FL (n=26)	58%	19%
RTX-refractory FL, ≥2 prior therapies (n=21)	67%	24%
	ORR	CR
MZL (n=9)*	78%	44%

#### mDoR and mPFS\*

#### **Median DoR:**

- 13.6 months for all responders (n=45)
- 32.0 months for complete responders (n=22)
- Median follow-up for responders of 30 months

#### **Median PFS:**

- 8.8 months overall (n=74)
- 9 months in patients with FL (n=57)



# LYMRIT 37-01 – Part A: Well-tolerated and 'benign' safety profile in elderly and frail patient population



#### Patient characteristics (n=74)

- Elderly (median 68 years)
- Heavily pre-treated with advanced-stage disease at baseline
- Primarily FL (n=57) with other NHL types (n=17)

#### Betalutin® was well tolerated

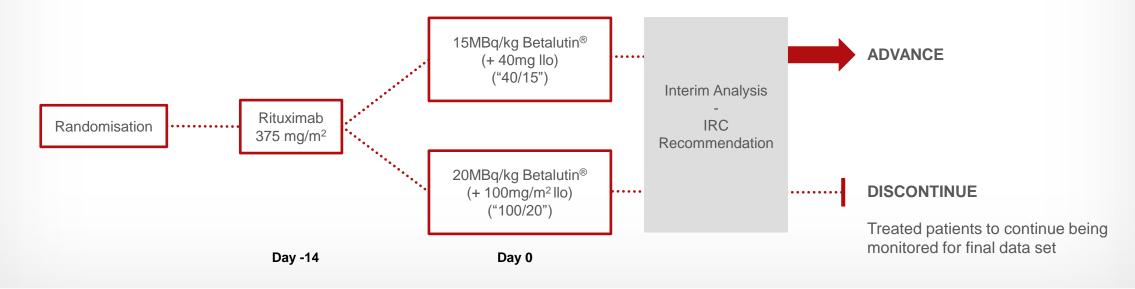
- Most common grade 3/4 AEs were transient and reversible neutropenia and thrombocytopenia
- Serious AEs occurred in 14 patients (19%)
- No cases of febrile neutropenia, low incidence of platelet transfusion and no study related deaths



# PARADIGME: focused on "40/15" arm following positive Interim Analysis



- Patient population: 3L FL patients who are refractory to anti-CD20 therapy difficult-to-treat population, typically >70 years of age, fragile, bulky disease and often with serious co-morbidities
- Primary endpoint: Overall response rate (ORR)
- Secondary endpoints: Duration of response (DoR), Progression free survival (PFS), Overall survival (OS), Quality of life (QoL)



- 73 patients were enrolled as of 17 February 2021 (59 as of 18 November 2020)
- Trial reduced to 120 patients 47 more patients in "40/15" arm needed to complete trial
- 95 sites in 24 countries open for enrolment



### Improved trial execution – No. 1 priority

- Protocol amendments are now being implemented following approval in all 24 countries
- A broadening of the inclusion criteria has increased the pool size of eligible patients by est. 30–50%
- Decision to make PARADIGME a single-arm trial has led to a reduction in patient numbers needed to complete PARADIGME and for BLA filing – 47 more patients needed
- Site-specific action plans have been implemented: senior leadership at NANO and CRO deeply involved in continuous monitoring of site performance metrics
- CMO is hosting virtual meetings with trial investigators/teams to promote PARADIGME
- Specialist firm appointed to focus on further improving the rate of recruitment, including targeted social media campaigns, especially in the US
- Competition for 3L FL patients reduced with completion or suspension of pivotal trials for CAR-T, Pi3k inhibitor and bispecific antibody candidates
- Vaccination roll out is expected to reduce restrictions imposed by COVID-19, particularly in relation to patients having access to hospitals





- BLA filing with FDA for Accelerated Approval based on PARADIGME data and initiation of confirmatory Phase 3 trial
- Orphan Drug Designation for 3L FL granted in US and EU in 2014
  - Fast-track designation granted in the US in June 2018 for 3L FL (and in June 2020 for R/R MZL)
  - Promising Innovative Medicine (PIM) designation granted in the UK in October 2018
- Exploring other routes to bring Betalutin<sup>®</sup> to patients faster to patients











Its unique product profile positions Betalutin® as the treatment of choice for elderly and frail patients, ~70% of all 3L+ FL pts.

**Approved Agents** 

Immunotherapy + Immunomodulatory
Rituximab-Lenalidomide
(combo)

Radioimmunotherapy
90Y-ibritumomab tiuxetan
(single agent)

Stem cell transplantation HDCT + ASCT Immunochemotherapy
Rituximab-CHOP, CVP, Chlorambuci
Obinutuzumab-Bendamustine
(combo)

Pi3k inhibitors

Idelalisb
Copanlisib
Duvelisib
Umbralisib
(single agents)

2<sup>nd</sup> gen Pi3k inhibitors

Parsaclisis

**EZH2** inhibitors

**Tazemetostat** (single agent)

Immunotherapy Rituximab

(single agent)

Young (50-60 yrs) & fit

Elderly & fit (60-65 yrs)

Elderly (>65 yrs) & frail

CAR-T therapy
Tisagenlecleucel
Axicabtagene ciloleucel

(reengineered T-cells + chemo)

ne ciloleucel Zandelisib
(single agents)

#### **Bispecific antibodies**

Odronextamab
Mosunetuzumab
Glofitamab
Epcoritamab
(single agents)

Agents in Development

#### **Betalutin**®

(single-dose radioimmunotherapy)

- Positioned to serve the unmet needs of the ~70% of 3L+ FL patients who are elderly/frail, resistant or refractory to anti-CD20 immunotherapy
- These patients have co-morbidities, that prevent the use of both chemotherapy and other therapies (incl. Pi3k inhibitors, CAR-T cell therapies and bispecific antibodies) associated with a high side-effect burden
- Delivers durable responses with a gentler safety profile, with a one-time administration





- Efficacy observed in LYMRIT 37-01 Part A is seen as a major strength
  - The response rate and mDoR in complete responders are viewed as compelling by HemOncs\*
- The combination of potential benefits is what sets Betalutin® apart
  - One-time treatment + durable efficacy + manageable and 'benign' safety profile + simplicity for patients and physicians
- HemOncs\* view frail/elderly patients with co-morbidities (that prevent chemotherapy or other therapies with high side-effect burden), including patients refractory to RTX/anti-CD20, as Betalutin®'s ideal patients





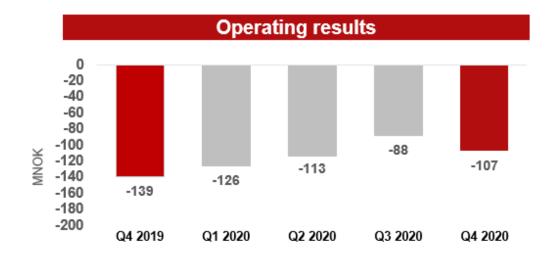
### **FINANCIALS**



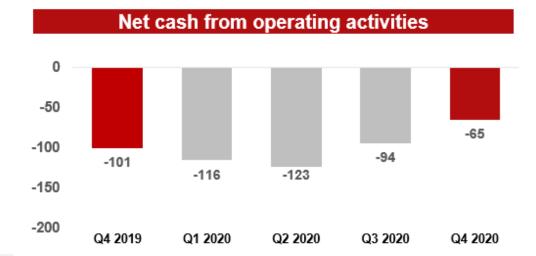


### Investing in Betalutin®





 Operating results NOK -106.8 million (Q4'2019: NOK -139.3 million)

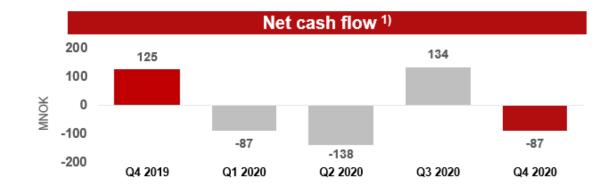


Net cash from operating activities
 NOK -65.2 million (Q4'2019: NOK -100.5 million)



### Cash runway extended into Q3'2021







- Net cash from operating activities of NOK -65.2 million (Q4: NOK 105.5 million)
- Net cash flow from investing activities of NOK 1.4 million (Q4: NOK 4.7 million)
- Net cash flow from financing activities of NOK -19.3 million (Q4: NOK 221 million)
- Effects of exchange rate changes on cash and cash equivalents
   NOK -3.6 million (Q4: NOK 0.2 million)
- Cash and cash equivalents amounted to NOK 294 million end of December 2020



<sup>\*</sup> USD/NOK 8.82



WE ARE 100% FOCUSED ON DELIVERING SIGNIFICANT VALUE FROM BETALUTIN®





## Highly confident in the potential of Betalutin® to fulfil important unmet needs in FL

- Goal to complete PARADIGME targeting preliminary 3-month top-line data in H2'2021
  - Reduced trial size means 47 patients now needed to complete PARADIGME and for BLA filing
- Significantly improved rate of patient recruitment into PARADIGME despite COVID-19
  - Inclusion criteria for PARADIGME have been broadened, based on its 'benign' safety profile
  - Recent new initiatives expected to further enhance the rate of recruitment
- Promising clinical efficacy and safety data seen from a one-time administration in R/R iNHL
- Betalutin<sup>®</sup> is a 100% owned asset targeting a total NHL opportunity of USD 26.1 billion by 2026\*
  - Actively pursuing flexible regional commercialisation strategy to maximise value







Annual General Meeting	15 April 2021
Q1 2021 results	26 May 2021
Q2 and H1'2021 results	27 August 2021

<sup>\*</sup>Dates subject to change. The time and location of the presentations will be announced in due time.

- A two-week quiet period takes place ahead of full year and quarterly results
- Please send Investor Relations enquiries to <u>ir@nordicnanovector.com</u>





## THANK YOU

### QUESTIONS?

