

Q2 AND H1'2020 REPORT HIGHLIGHTS AND FINANCIALS

AUGUST 27<sup>TH</sup>, 2020

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## Forward-looking statements

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- Strategic review completed with focus on advancing PARADIGME and extending cash runway into 2021
- Pivotal Phase 2b PARADIGME trial with Betalutin® progressing in 3<sup>rd</sup>-line Follicular Lymphoma (FL)
  - 56 patients enrolled (August 26<sup>th</sup>) enrolment rate still affected negatively by COVID-19
  - Maintain target to recruit 130 patients
- Protocol amendments to PARADIGME being implemented to enlarge eligible patient population and increase rate of enrolment
  - Decision based on reviewed FDA discussions
- Betalutin® granted Fast-track (US) and Orphan Drug (EU) designations for Marginal Zone Lymphoma (MZL)



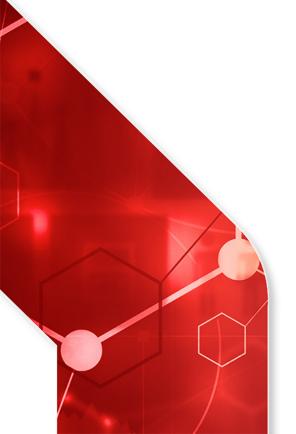
### Events after H1'2020

- Outcome of Interim Analysis Recommendation to focus on "40/15" dosing arm
  - Comprehensive review of interim data by Independent Review Committee
  - Both arms were active based on efficacy measures of CR, PR and SD
  - "40/15" arm demonstrated consistency across all sub-groups
  - "100/20" arm to be discontinued dosed patients to be monitored for the remainder of the trial
  - Maintain target to recruit 130 patients
- Clear plan to implement protocol amendments and other initiatives to increase patient enrolment
  - Target 3-month top-line data in H2'2021 (despite COVID-19)
  - Paves the way for a planned regulatory filing with Betalutin<sup>®</sup>
- Dr Christine Wilkinson Blanc appointed as Chief Medical Officer
  - 25+ years' clinical development experience in oncology/haematology with pharma and biotech





### FOCUS ON ADVANCING PARADIGME





# Revised clinical development strategy to capture 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 R/R MZL based on:
  - Promising response in LYMRIT 37-01
  - Clear unmet need reflected in Fast-track (US) and Orphan Drug (EU) designations

# To be paused after completing ongoing cohorts

#### Archer-1

#### Betalutin® + RTX in 2L R/R FL

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

**LYMRIT 37-05** 

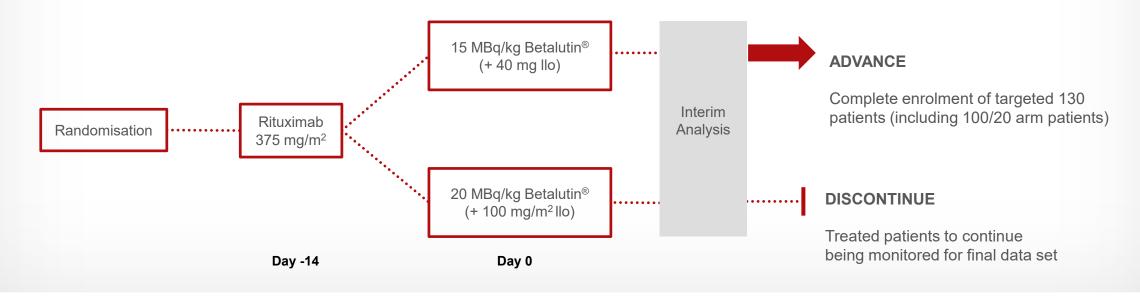
#### Single-agent Betalutin® in DLBCL

- · Recruitment is very slow
- DLBCL remains an important indication need to evaluate optimal development strategy
- All pre-clinical and research initiatives to be paused





- **Patient population**: 130 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)



- 56 patients have been enrolled (as of August 26<sup>th</sup>)
- 95 sites in 24 countries open for enrolment





- Focus on advancing "40/15" arm and increasing rate of enrolment
- Protocol amendments being implemented following FDA discussions
  - Significantly enlarges eligible patient population, e.g. allow inclusion of FL patients who have had SCT
    - SCT is frequently used for treating R/R FL and, in some countries\*, SCT patients make up the majority of 3L FL patients
  - Estimate 2-3 months to gain approval in all 24 countries
  - Enrolment to continue under existing protocol until amendments approved
- Enhanced working relationship with CRO and interactions with study investigators
  - Implemented better patient referral networks
- Targeting three-month data readout in H2'2021





- Although we see improvements in certain geographies, the negative impact due to COVID-19 continues to impact PARADIGME patient recruitment during Q3
- Target patient population is a high-risk group for COVID-19
  - Restrictions on movement during lockdown prevented follow-up visits and data collection on existing patients, and dosing of newly enrolled patients
- Easing of COVID-19 lockdown enabling cancer clinical trials to restart
- Expect better enrolment rate due to protocol amendments and initiatives which have been implemented





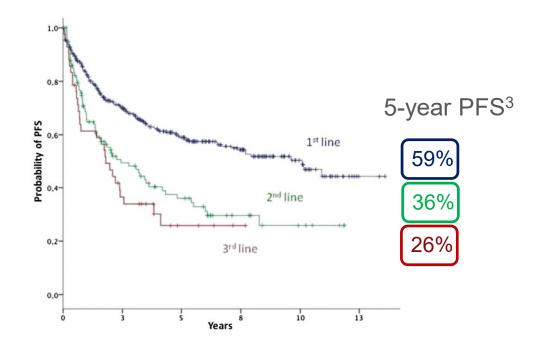
BETALUTIN® POTENTIAL TO ADDRESS UNMET NEED IN FL





## NHL – the need for new treatment options

- 40-60% indolent NHL patients treated with RTX-containing regimen are either refractory (10%) or develop resistance within 5 years
- R/R patients may not tolerate chemotherapy because of age or co-morbidities
- The need: Alternative target to CD20 + "chemo-free" regimens with gentle side-effect profile



FL: 5-year overall survival for RTX-refractory patients vs all: 58%<sup>1</sup> vs 88%<sup>2</sup>

MZL: Patients with refractory or relapsed MZL have poor outcomes with current approaches<sup>4</sup>

~40% of DLBCL patients relapse following 1L RTX-chemo; 60-70% of these patients fail or are unsuitable for subsequent high-dose chemo + SCT



<sup>&</sup>lt;sup>1</sup>Abdollahi S et al, Blood 2008:112 <sup>2</sup>seer.cancer.gov (2019)

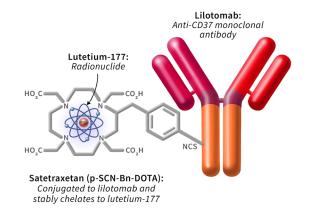
<sup>&</sup>lt;sup>3</sup>Rivas-Delgado A et al. EHA 2017; abstract 405

<sup>&</sup>lt;sup>4</sup> Current Treatment Options in Marginal Zone Lymphoma, The American Journal of Hematology/Oncology, vol. 13, no. 5, 2017

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



# Betalutin®: A novel CD37-targeting radioimmunotherapy



- CD37 is highly expressed in B-NHL<sup>1</sup>
- 177Lu: 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

#### Single-dose treatment

Promising and durable response from a single dose in elderly and heavily pre-treated NHL patients

Predictable and manageable side effect burden, important for NHL patients who might not tolerate chemotherapy

Alternative target to CD20, well suited for NHL patients who become refractory to RTX-based regimens



Strong Betalutin® side-effect profile positions it for frailer/older 3L+ FL patients

**Approved Agents** 

Immunotherapy + Immunomodulatory **RTX-Lenalidomide** 

Radioimmunotherapy (single agent) Zevalin

Stem cell transplantation **HDCT + ASCT** 

**Immunochemotherapy** Rituximab-chemotherapy **Obinutuzumab-chemotherapy**  Pi3k inhibitors (single agent) Idelalisib Copanlisib **Duvelisib** 

**EZH2** inhibitors (single agent) **Tazemetostat** 

**Immunotherapy** (RTX single agent) Rituximab

Young (50-60 yrs) & fit

Elderly & fit (60-65 yrs)

Elderly (>65 yrs) & frail

**CAR-T** therapy **Kvmriah** 

> Bispecific antibodies **REGN1979** Mosunetuzumab **Epcoritamab**

Agents in Development

2<sup>nd</sup> gen Pi3k inhibitors (single agent) **Umbralisib Parsaclisib** MEI-401

#### Betalutin<sup>®</sup> single-dose radioimmunotherapy

- Positioned to serve the unmet needs of elderly/frail R/R FL patients, in particular, those refractory to anti-CD20 immunotherapy
- These patients have **co-morbidities**, that **prevent** chemotherapy or targeted therapies (i.e. Pi3K inhibitors) with a high side-effect burden
- Delivers durable responses with a gentler safety profile, in a single administration





# COST-SAVING INITIATIVES AND CORPORATE REORGANISATION





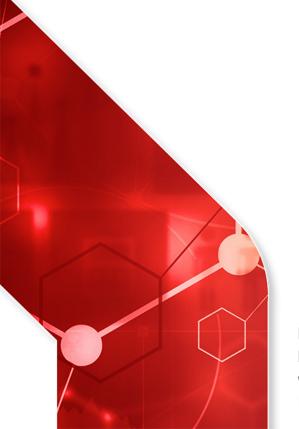


- Changes to the management team interim CEO, CFO and CMO
- Headcount reduced by approx. 20%
- Cost savings of approx. NOK 35 million in connection with the restructuring on an annual basis
- Increased involvement Board of Directors



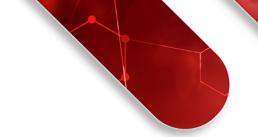


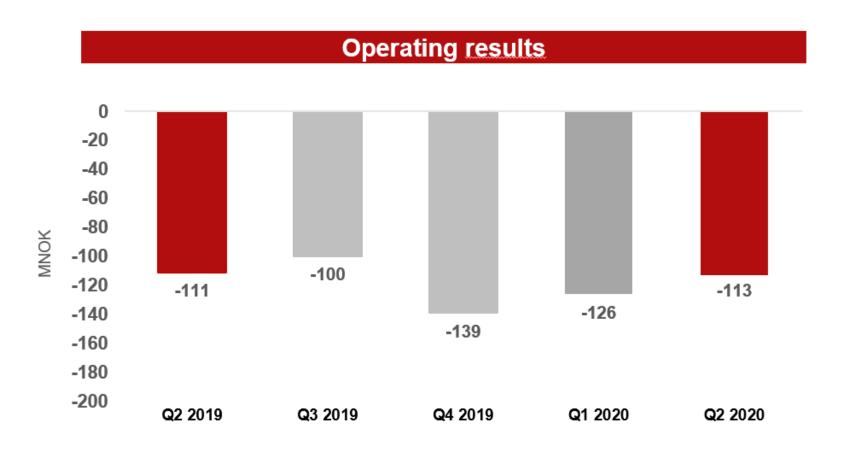
FINANCIAL RESULTS FOR Q2 AND H1'2020







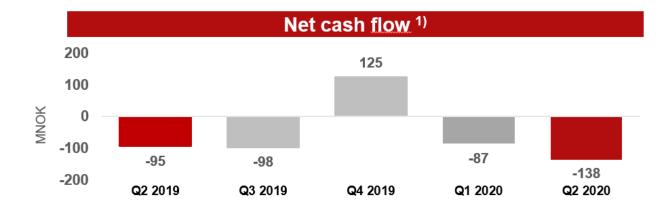


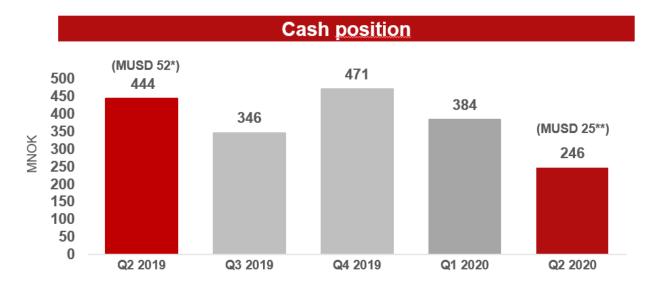


- Q2'20 spending on par with Q2'19
- The impact of cost savings of NOK 35 million will materialise during H2'20



## Cash runway extended into 2021





- Net cash from operating activities of NOK -123.2 million (Q4: MNOK -116.0)
- Cash and cash equivalents amounted to NOK 246.2 million end of June 2020



<sup>\*</sup> USD/NOK 8.51 \*\* USD/NOK 9.75

<sup>1)</sup> Net cash flow from operating, investing and financing activities plus/minus currency effect





Q3 2020 results	19 November 2020
Q4 and FY 2020 results	February 2021
Q1 2021 results	May 2021

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>





- Goal to complete PARADIGME as quickly as possible despite COVID-19 situation
- Targeting readout of 3-month top-line data from PARADIGME in H2'2021
- Recommendation from IRC on Interim Analysis has provided clarity on advancing PARADIGME
- Protocol amendments being implemented and approval sought in all 24 countries
  - Working closely with CRO to implement other initiatives to speed up enrolment
- Our confidence in potential of Betalutin® to fulfil important unmet needs in NHL remains unchanged





# Questions

