

### Q1'18 HIGHLIGHTS AND FINANCIALS

MAY 30<sup>TH</sup>, 2018

TONE KVÅLE, CFO & INTERIM CEO
LISA ROJKJAER, CMO







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#### Focused on the development of targeted therapies for haematological cancers

#### Lead candidate Betalutin® for treating NHL

- Novel anti-CD37 therapy in pivotal Phase 2b trial (PARADIGME) in 3L R/R FL read-out expected 1H 2020
- Promising efficacy with encouraging duration of response and favourable safety profile seen in earlier trials
- Potential for Betalutin<sup>®</sup> in other NHL indications

#### Clear plan to bring Betalutin® to market

- Designed to enhance chances of Betalutin® gaining regulatory approval with a competitive product profile
- Intent to independently commercialise Betalutin<sup>®</sup> in major markets

#### Listed on Oslo Stock Exchange (OSE: NANO)

Cash resources through 1H 2020



## Q1'18 and post-period highlights

- Luigi Costa stepped down as CEO (April) search for new CEO progressing
  - Tone Kvåle appointed Interim CEO and continues as CFO
- PARADIGME pivotal Phase 2b trial (Betalutin<sup>®</sup> in 3L R/R FL)
  - Start-up activities and patient screening underway, first patient expected 1H 2018
  - April update timelines revised with first results targeted for 1H 2020 (previously 2H 2019)
- Humalutin<sup>®</sup> (<sup>177</sup>Lu-conjugated chimeric anti-CD37 antibody in NHL)
  - Clinical development on hold
- Management team strengthened with dedicated IR and capital markets expertise
  - Malene Brondberg appointed as Vice President, IR and Corporate Communications





BETALUTIN® – BUILDING A COMPETITIVE PROFILE IN FL AND NHL



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# Single-agent Betalutin® is highly active in FL patients, especially in 3L



#### Response rates by subgroup and treatment arm

	ORR (CR + PR)	CR	
All patients (n=62)	60%	24%	
All FL patients (n=47)	64%	23%	
Arm 1 (40/15) (n=25)	68%	28%	
Arm 4 (100/20) (n=8)	50%	25%	
FL with ≥2 prior therapies (3L FL) (n=32)	66%	25%	

#### **Median duration of response**

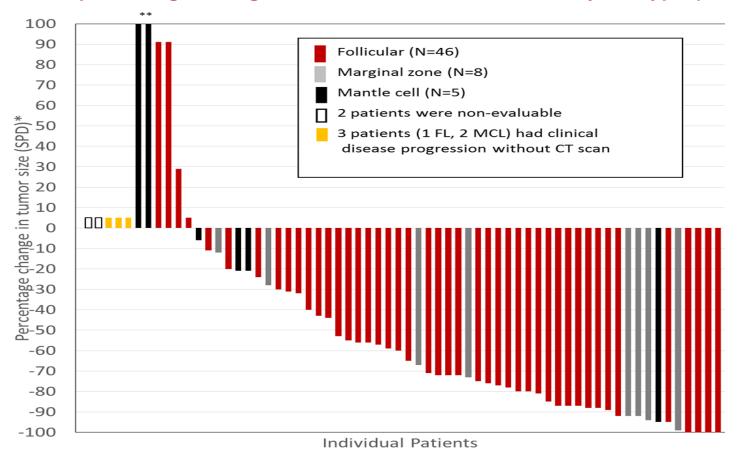
	Median DoR
All iNHL patients (n=37)	13.3m
iNHL CR patients (n=15)	20.5m
All FL patients with 40/15 (n=17)	13.3m
FL CR patients with 40/15 (n=7)	22.9m

- Published data from the LYMRIT 37-01 Phase 1/2a trial\*
- Population of primarily elderly, heavily pre-treated patients with advanced stage disease
- Patients with CR remain disease-free for a median of over 20.0 months with one-time Betalutin<sup>®</sup> administration



## 90% of evaluable patients had a decrease in tumour size

#### Best percentage change in tumour size from baseline by subtype (n=59)



<sup>\*</sup>SPD = sum of the products of the diameters.



<sup>\*\*</sup>Change in size of target lesion is beyond the scale for this figure (n=2).

## Betalutin® is well-tolerated, with a manageable safety profile



#### Grade 3/4 TEAEs in ≥2 patients (n=64)

Adverse Event	n (%)²
Neutropenia <sup>1</sup>	35 (55%)
Thrombocytopenia <sup>1</sup>	32 (50%)
Leukopenia <sup>1</sup>	32 (50%)
Lymphopenia <sup>1</sup>	22 (34%)
Infections Urinary tract infection (1) Sepsis/neutropenic sepsis (2) Pharyngitis (1) Pneumonia (1)	5 (8%)
Lymphoma progression	3 (5%)
Serious Adverse Event (SAE)	
Thrombocytopenia	2 (3%)
Atrial fibrillation	2 (3%)
Lymphoma progression	2 (3%)

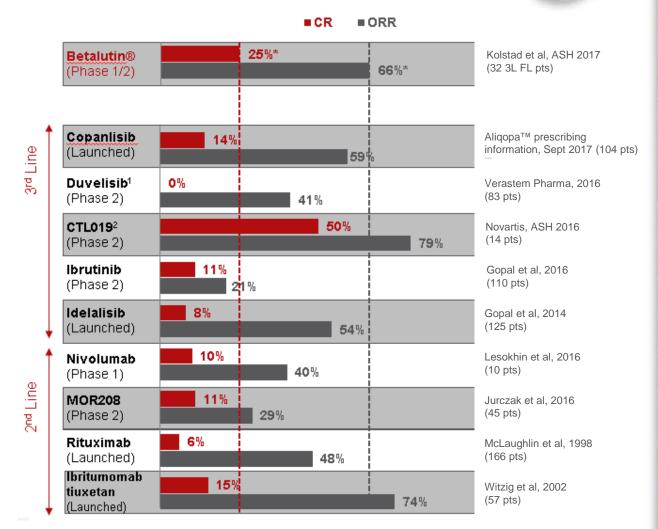
<sup>1.</sup> Including events reported as 'investigations'. 2. Two patients had not had hematologic recovery at the time of data cut-off.

- Overall, Betalutin<sup>®</sup> was well-tolerated, in particular considering the median age of enrolled patients
- Most common grade 3/4 TEAEs are reversible thrombocytopenia and neutropenia
- Low incidence of G3/4 infections (<10%)</li>
- One report of MDS/CMML in a patient with prior alkylating agent exposure





- Clear need for new effective and well-tolerated therapies for patients who become refractory to rituximab, especially the elderly
- Single-agent Betalutin® shown to be well-tolerated and active in recurrent indolent NHL (LYMRIT 37-01 Phase 1/2a trial)
- With its promising clinical profile and ready-to-use formulation, Betalutin<sup>®</sup> has the potential to be a novel, safe and effective therapy for recurrent NHL
- Final analysis from LYMRIT 37-01 study (n=74) expected in 2H 2018, targeting ASH 2018 for readout (December)



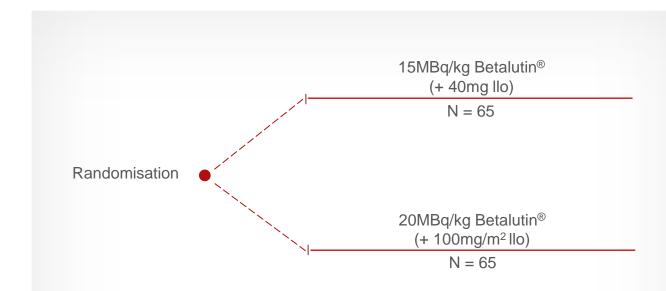


## Insight from pre-commercial research – defining optimal commercialisation strategy for success

- The value of Betalutin<sup>®</sup> as a new treatment option in NHL is clearly perceived
  - Efficacy is seen as a major strength
  - The combination of efficacy, manageable toxicity and simplicity makes Betalutin<sup>®</sup> truly appealing
  - It allows Betalutin<sup>®</sup> to enter an unsatisfied area of the market, and is well positioned to serve unmet needs among difficult-to-treat, refractory patients
- Clear strategies to maximise the clinical and commercial potential of Betalutin<sup>®</sup>
  - Pre-launch scientific engagement of key institutions and thought leaders on the benefits of the technology
  - Well-designed clinical development plan, aligned with health authority feedback
  - Robust market access and reimbursement programme
  - Optimised referral pathway
  - Streamlined manufacturing and distribution via a centralised logistics partner



## PARADIGME: Seamless design for a robust dose selection aligned with regulatory feedback



- Target is 130 patients at 80-85 sites in approximately 20 countries
- Primary endpoint: Overall response rate (ORR)
- **Secondary endpoints**: Duration of response (DoR), Progression free survival (PFS), Overall survival (OS), Safety, Quality of life

- Two potential Betalutin<sup>®</sup> dosing regimens have emerged from LYMRIT 37-01 based on safety, efficacy and dosimetry data
- These will be compared with the goal to select the best Betalutin<sup>®</sup> dosing regimen
- Patient population: 3L FL patients who are refractory to anti-CD20 based therapy
- Seamless design approach based on data from the first part of the 37-01 study – more efficient than separate Phase 2 trial





- PARADIGME aims to recruit 130 3L R/R FL patients in 80-85 sites in 20 countries
  - First patient is expected to be dosed in 1H 2018
- As at May 29<sup>th</sup>, 2018, 23 clinical sites in 8 countries are open for enrolment
  - US sites expected to be open mid-year
  - Sites selected are clinical centres of excellence in the treatment of NHL and haematological malignancies
- Norway CTA update
  - As at May 29<sup>th</sup> Paradigme is fully approved in Norway





#### Key objectives:

- 1. Complete site activation as fast as possible
- 2. Start patient screening as soon as each site is activated
- 3. Sustain the highest possible enrolment rate

#### Key action items:

- Fully leverage and reinforce Medical Science Liaison (MSL) organisation now deployed in Europe & USA
- Deployment of study nurses/associates within high-traffic sites to help investigators identify patients
- Partner with non-for-profit (i.e. Leukemia and Lymphoma Society) and other third-party organisations with experience in patient enrolment programmes
- Meetings and regular webcasts with Investigators to maintain high level of attention on PARADIGME



### PARADIGME timelines and expectations

## - revised in April



- Now targeting initial efficacy and safety data read-out for PARADIGME in 1H 2020 (previously 2H 2019)
- Targeting first regulatory filing in 2020
- Exploring ways to bring Betalutin<sup>®</sup> to patients quicker, e.g. via fast track, PRIME, breakthrough therapy designation (BTD)
- Financial resources are expected to be sufficient until data read-out from PARADIGME



# Clinical development of Betalutin® in NHL: maximising its value potential



Targeted indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
3L FL (PARADIGME)	Pivotal Phase 2	?b			
2L FL, combination w/ rituximab (Archer-1)	Phase 1b				
R/R DLBCL, SCT ineligible (LYMRIT 37-05)	Phase 1				
iNHL dosimetry (LYMRIT 37-02)	Phase 1				

- Priority focus on ongoing Betalutin® clinical development programmes
- Potential future opportunities in Betalutin<sup>®</sup> life-cycle management indications (R/R DLBCL conditioning, other NHL subtypes)
- Potential for other CD37-targeting therapies, including Humalutin® (a Phase 1-ready asset)



## Archer-1: Betalutin® + rituximab (RTX) combination in 2L FL

- Explore Betalutin® + RTX combination in 2L NHL
  - RTX anti-CD20 immunotherapy is established standard of care in NHL
  - Approx. 8,980 (US) + 7,000 (EU-5) patients in 2014\*
  - In preclinical model of NHL, Betalutin® + RTX inhibited tumour growth significantly and prolonged overall survival

#### Phase 1b trial

- A robust approach to generate safety, tolerability, pharmacokinetic and initial efficacy data in patients
- CTA approved by NoMA, pending approval by REK
- Start-up activities will commence upon regulatory approval
- Expect first patient dosed in 2H 2018



# LYMRIT 37-05: Betalutin® in R/R DLBCL patients not eligible for stem cell transplantation (SCT)



- Explore Betalutin<sup>®</sup> single administration in DLBCL
  - DLBCL is an aggressive form of NHL and accounts for up to 43% of NHL
  - Estimated 14,000 patients (US, EU-5 and Japan)\*
  - ~40% DLBCL patients relapse after 1L rituximab-chemotherapy and 60-70% relapsed patients fail or are unsuitable for subsequent high-dose chemotherapy followed by SCT
  - Few therapeutic options for patients NOT eligible for SCT
- On-going Phase 1 open label, single-administration, ascending-dose study
  - Objective to identify optimal dosing regimen for Phase 2 studies
  - Up to 24 patients planned to be enrolled in the US and EU
  - Started Q1 2017; first read-out targeted for 2H 2018





### FINANCIALS AND SUMMARY



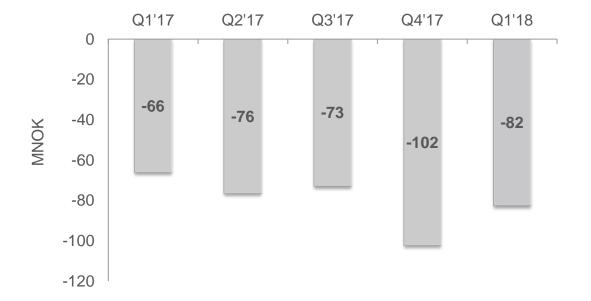
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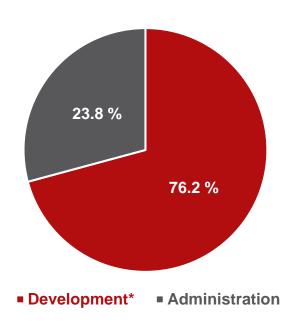




#### **Operating result**



#### **Operating expenses YTD March 2018**

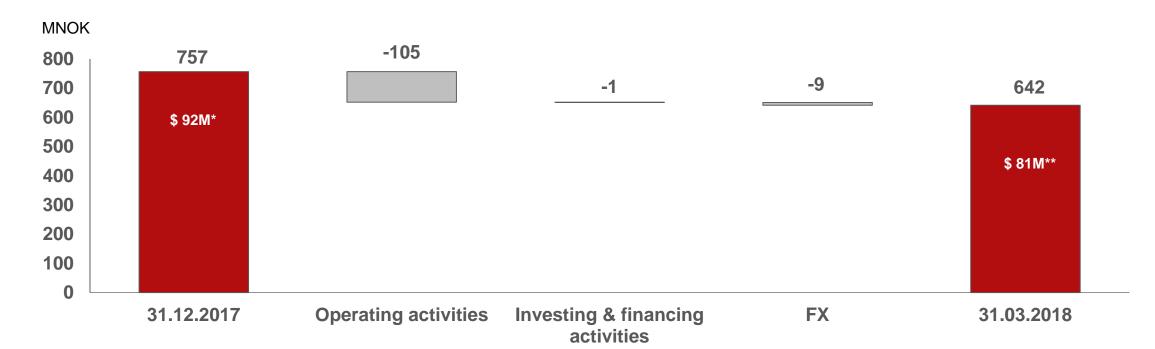


\*Development costs: preclinical, clinical, medical affairs, regulatory and CMC activites



## Solid cash position, expected to be sufficient to reach data read-out for PARADIGME in 1H 2020





<sup>\*</sup> USD/NOK 8.24



<sup>\*\*</sup> USD/NOK 7.97





1H 2018	Betalutin <sup>®</sup> in 3L FL	PARADIGME: First patient dosed
2H 2018	Betalutin® + rituximab in 2L FL	Archer-1: First patient dosed*
2H 2018	Betalutin® in R/R iNHL	LYMRIT 37-01: Complete final analysis and first data read-out
2H 2018	Betalutin® in DLBCL	LYMRIT 37-05: Preliminary data read-out
1H 2020	Betalutin <sup>®</sup> in 3L FL	PARADIGME: Data read-out





### Financial calendar

Q1 2018 meeting (in Norwegian)	May 31 <sup>st</sup> , 2018
Q2 2018 results	August 22 <sup>nd</sup> , 2018
Q3 2018 results	November 21 <sup>st</sup> , 2018
Q4 and FY 2018 results	February 2019

Dates subject to change. The time and location of the presentations will be announced in due time.

- A two-week quiet period has been introduced ahead of full year and quarterly results
- Please send Investor Relations enquiries to <a href="mailto:ir@nordicnanovector.com">ir@nordicnanovector.com</a>







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### Glossary

1L, 2L, 3L: First, second and third line of treatment

(A)SCT: (Autologous) stem cell transplant

**ADC:** Antibody-Drug-Conjugate

AHCP: Allied Healthcare Professional

**AML:** Acute Myeloid Leukemia

**APAC:** Asia-Pacific

**ARC:** Antibody-Radionuclide-Conjugate

ARCHER-1: Name of Nordic Nanovector's combination study; Betalutin® and

rituximab

**ASH:** American Society of Hematology

Authorized User: Physician authorized to prescribe and administer a

radiopharmaceutical drug

**B-cell:** A type of lymphocyte (white blood cell) in the humoral immunity of the body's adaptive immune system. Can be distinguished from other lymphocytes by the presence of a protein on the B-cell's outer surface known as a B cell receptor (BCR). This specialized receptor protein allows a B-cell to bind to a specific antigen.

**CD20:** B-lymphocyte antigen CD20 is an activated-glycosylated phosphoprotein expressed in the surface of all B-cells beginning at the pro-B phase and progressively increasing in concentration until maturity

**CD37:** B-lymphocyte antigen CD-37 is a protein, a member of the transmembrane 4 superfamily, also known as the tetraspanin superfamily of cell surface antigens

chHH1: Chimeric version of the HH1 antibody

**CLL:** Chronic Lymphocytic Leukemia

**CR:** Complete Response

**DLBCL:** Diffuse Large B-Cell Lymphoma

**DoR:** Duration of Response

**EANM:** European Association of Nuclear Medicine

EMA: European Medicines Agency

**EMEA:** Europe, Middle East, and Africa **FDA:** Food and Drug Administration (US)

FDG PET/CT: Positron emission tomography with

2-deoxy-2-[fluorine-18]fluoro- D-glucose integrated with computed tomography

FL: Follicular Lymphoma

**GMP:** Good Manufacturing Practice **Haem-Oncs:** Haematologist-oncologist

HCP: Healthcare Professional

HH1: Lilotomab

Humalutin®: Chimeric anti-CD37 ARC

ICML: International Conference on Malignant Lymhoma

**IND:** Investigational New Drug

iNHL: Indolent non-Hodgkin Lymphoma

KI: Kinase Inhibitor

**KOL:** Key Opinion Leader

**LCM:** Life-cycle management

**Lilotomab (Ilo):** Betalutin® consists of the radionuclide lutetium-177 conjugated to

the B-cell seeking anti-CD37 antibody lilotomab

Lu-177: Radionuclide lutetium-177

M.D: Medical Doctor

mAb: Monoclonal antibody

MBq: Megabecquerel (radioactivity measurement unit)



### Glossary

MCL: Mantle Cell Lymphoma

Medicare: US government reimbursement program for insured elderly

MedOnc: Medical oncologist
MoA: Mechanism of Action
MSL: Medical science liaison

nASCT: Not eligible for autologous stem cell transplant

**NCCN:** National Comprehensive Cancer Network

NDA: New Drug Application
NET: Neuroendocrine tumour
NHL: Non-Hodgkin's Lymphoma
NM: Nuclear medicine specialist

NNV003: Chimeric anti-CD37 antibody developed by Nordic Nanovector

**ODD:** Orphan Drug Designation

**ORR:** Overall Response Rate (CR plus PR)

OS: Overall Survival

PARADIGME: name of Nordic Nanovector's pivotal Phase 2b study

**PD:** Progressive Disease

**PFS:** Progression Free Survival

Pi3K: Phosphoinositide 3-kinase; class of Pi3K inhibitors include idelalisib,

copanlisib, duvelisib

PR: Partial Response

PRA: PRA Health Sciences, a clinical research and data analytics company

QoL: Quality of Life

R/R: Relapsed/refractory

R: Rituximab

RadOnc: Radiation oncologist

R-Benda/R-B/RB: Rituximab, bendamustine

**R-Chemo:** Combination treatment consisting of rituximab plus one (i.e., bendamustine, fludarabine) or more (i.e., CHOP, CVP) chemotherapy agents **R-CHOP:** Rituximab, hydroxydaunorubicin (doxorubicin), oncovin (vincristine),

prednisolone

R-CVP: Rituximab, cyclophosphamide, vincristine, prednisone

**RIT:** Radioimmunotherapy

R-Squared: Combination treatment consisting of rituximab plus lenalidomide

SAB: Scientific Advisory Board

Satetraxetan: International non-proprietary name for p-SCN-benzyl-DOTA

**SD:** Stable Disease

**SPECT/CT:** Single photon emission computed tomography (SPECT) integrated with computed tomography (CT)

**T-cell:** A type of lymphocyte (white blood cell) that plays a central role in cell-mediated immunity. Can be distinguished from other lymphocytes by the presence of a T-cell receptor (TCR) on the cell surface. They are called T-cells because they mature in the thymus

**TKI:** Tyrosine Kinase Inhibitor **TPP:** Target Product Profile

TTR: Time to Recurrence

**US**: United States

