

## Q1'18 HIGHLIGHTS AND FINANCIALS

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

TONE KVÅLE, CFO & INTERIM CEO

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# Forward-looking statements

This announcement contains certain forward-looking statements and forecasts based on uncertainty, 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 statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in these 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.

# Nordic Nanovector at a glance

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® 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® in major markets

Listed on Oslo Stock Exchange (OSE: NANO)

- Cash resources through 1H 2020

# Q1'18 and post-period highlights

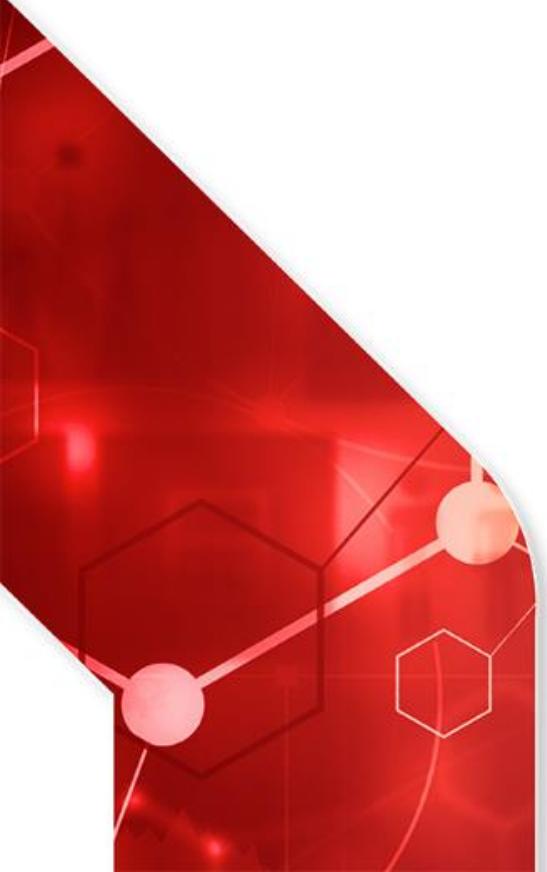
- Luigi Costa stepped down as CEO (April) – search for new CEO progressing
  - Tone Kvåle appointed Interim CEO and continues as CFO
- PARADIGME pivotal Phase 2b trial (Betalutin® in 3L R/R FL)
  - Start-up activities and patient screening underway, first patient expected 1H 2018
  - April update – timelines revised with first results targeted for 1H 2020 (previously 2H 2019)
- Humalutin® (<sup>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 $\geq 2$ prior therapies (3L FL) (n=32)	66%	25%

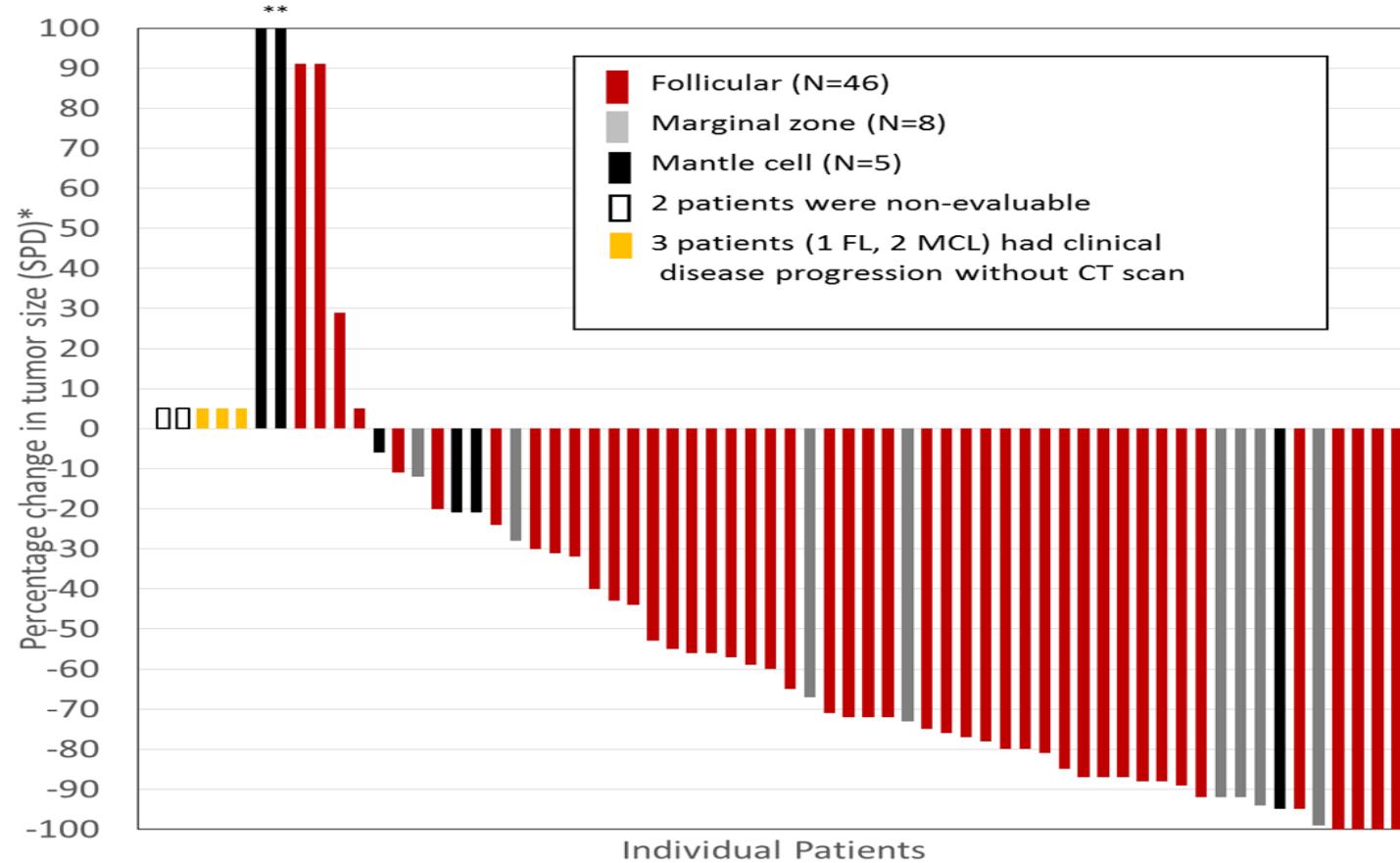
## Median duration of response

	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 LYM'RIT 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® administration

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

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



\*SPD = sum of the products of the diameters.

\*\*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)

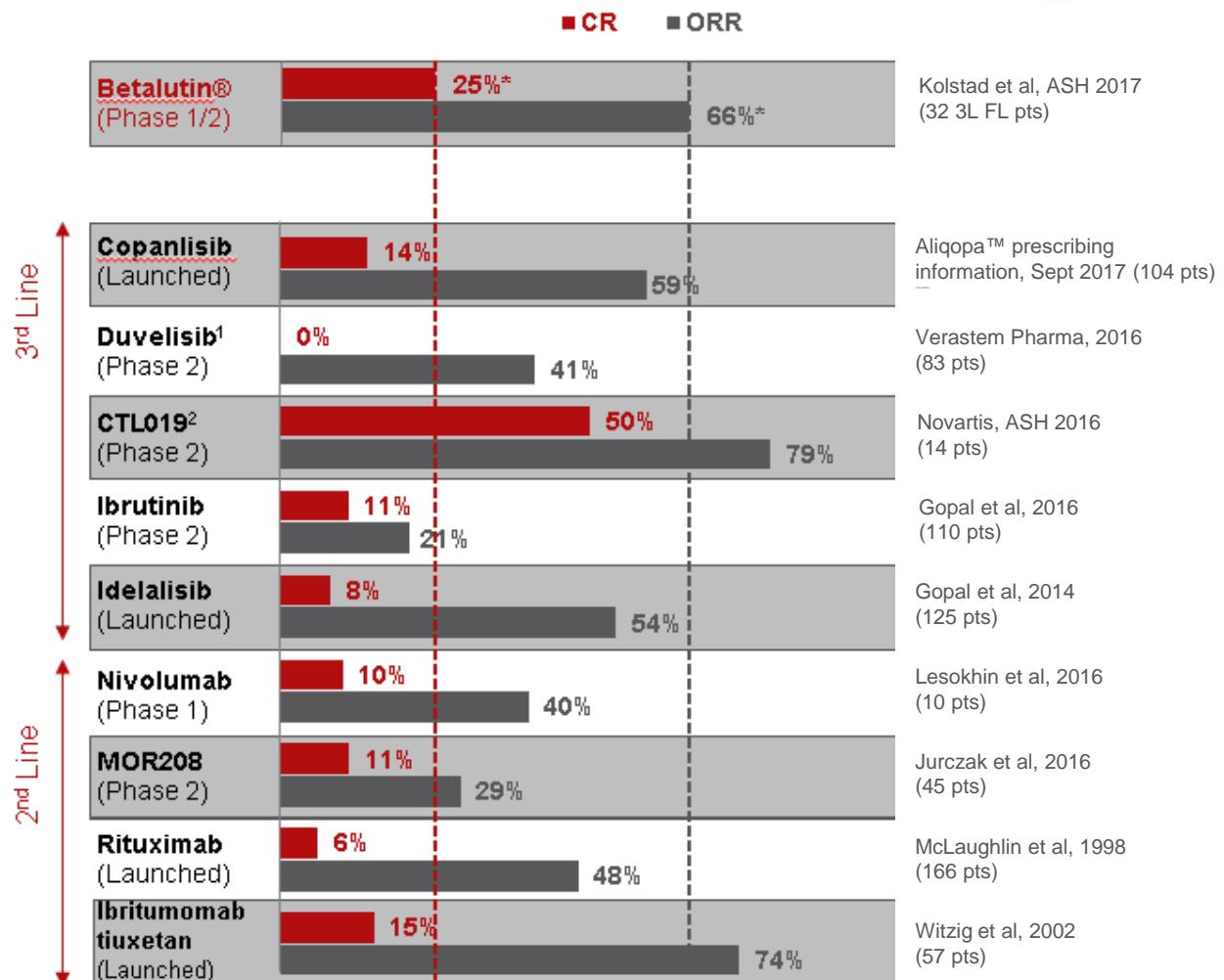
Adverse Event	n (%) <sup>2</sup>
Neutropenia <sup>1</sup>	35 (55%)
Thrombocytopenia <sup>1</sup>	32 (50%)
Leukopenia <sup>1</sup>	32 (50%)
Lymphopenia <sup>1</sup>	22 (34%)
Infections	
Urinary tract infection (1)	
Sepsis/neutropenic sepsis (2)	
Pharyngitis (1)	
Pneumonia (1)	
Lymphoma progression	5 (8%)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

- Overall, Betalutin® 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%)
- One report of MDS/CML in a patient with prior alkylating agent exposure

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

# Promising data support the potential of Betalutin®

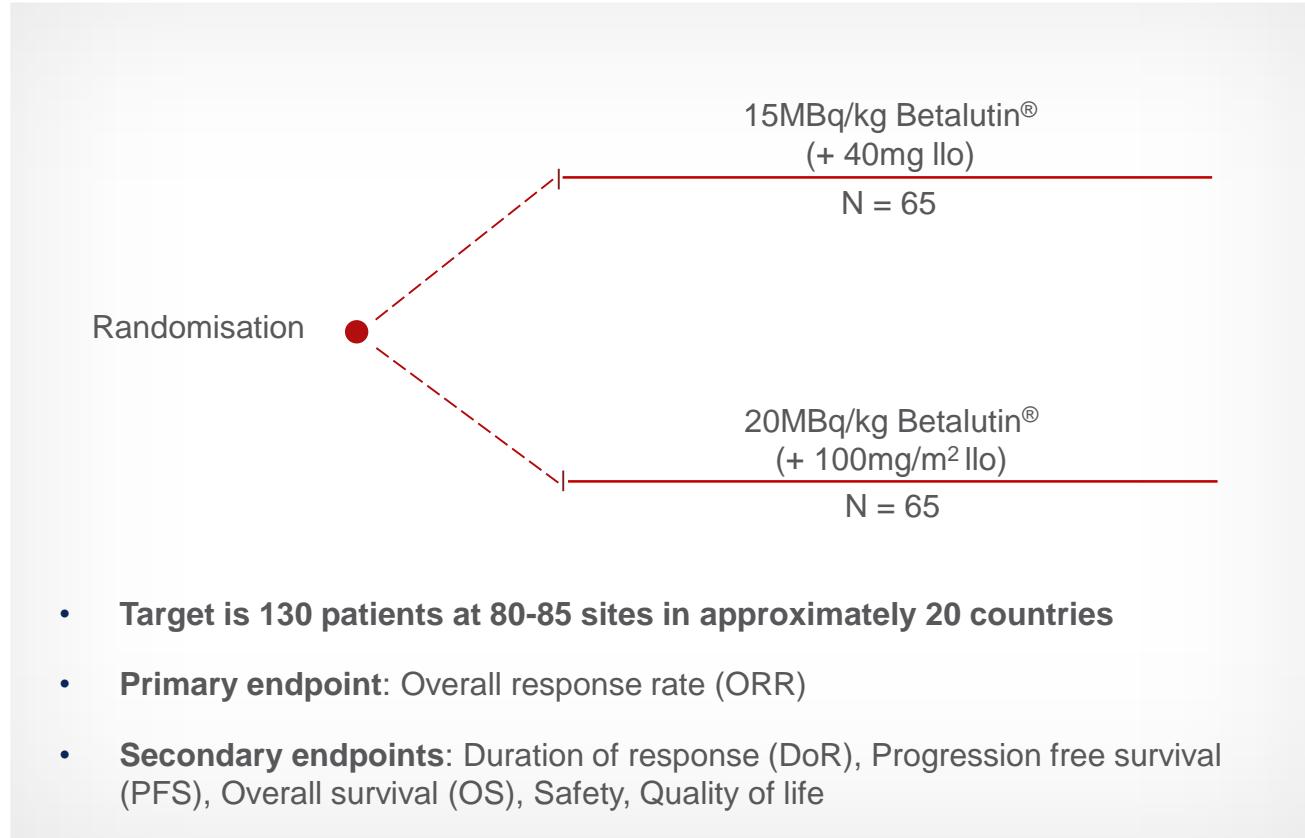
- Clear need for new effective and well-tolerated therapies for patients who become refractory to rituximab, especially the elderly
- Single-agent Betalutin® shown to be well-tolerated and active in recurrent indolent NHL (LYMRIT 37-01 Phase 1/2a trial)
- With its promising clinical profile and ready-to-use formulation, Betalutin® 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 read-out (December)



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

- The value of Betalutin® 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® truly appealing
  - It allows Betalutin® 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®
  - 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



- Two potential Betalutin® 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® 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 status

- 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

# Our activities aimed at driving enrolment

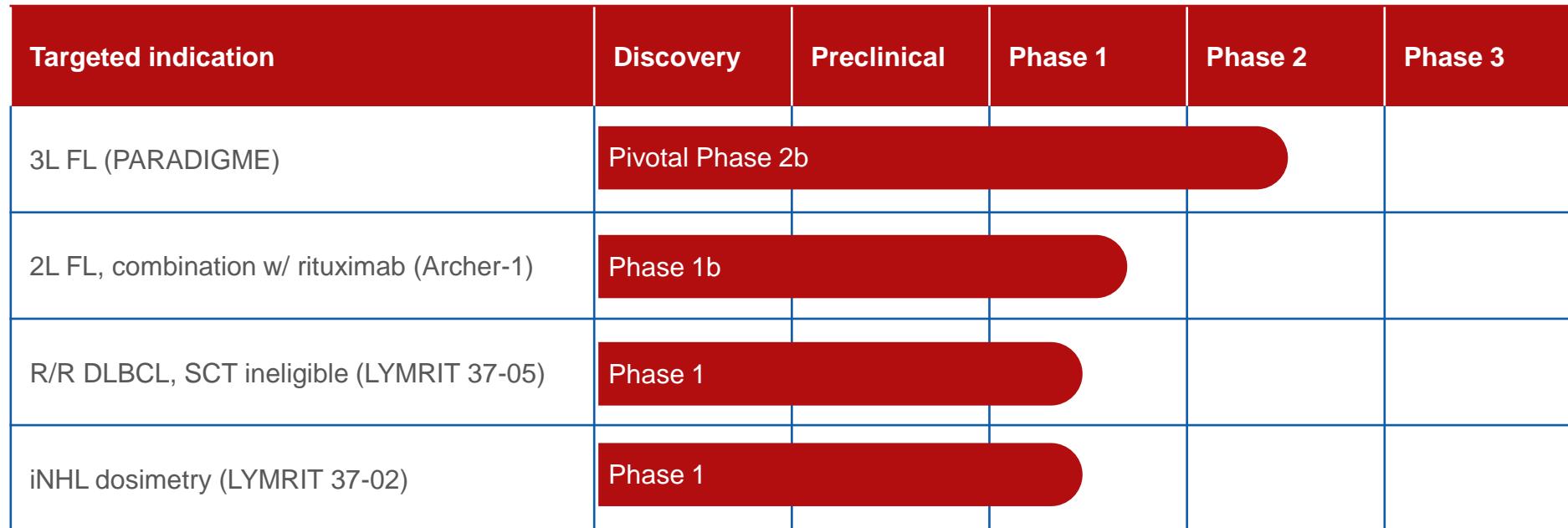
- Key objectives:
  1. Complete site activation as fast as possible
  2. Start patient screening as soon as each site is activated
  3. Sustain the highest possible enrolment rate
- Key action items:
  - Fully leverage and reinforce Medical Science Liaison (MSL) organisation now deployed in Europe & 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® 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



- Priority focus on ongoing Betalutin® clinical development programmes
- Potential future opportunities in Betalutin® 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

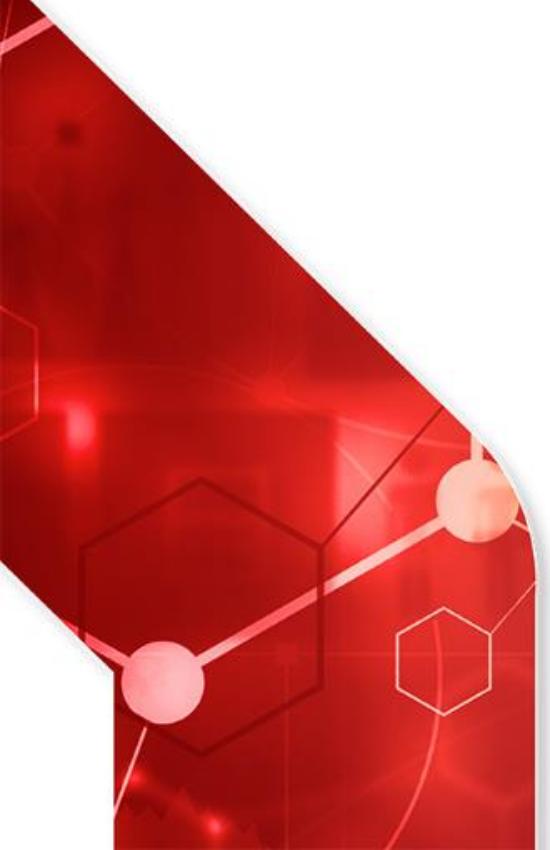
# LYMRIT 37-05: Betalutin® in R/R DLBCL patients not eligible for stem cell transplantation (SCT)

- Explore Betalutin® 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

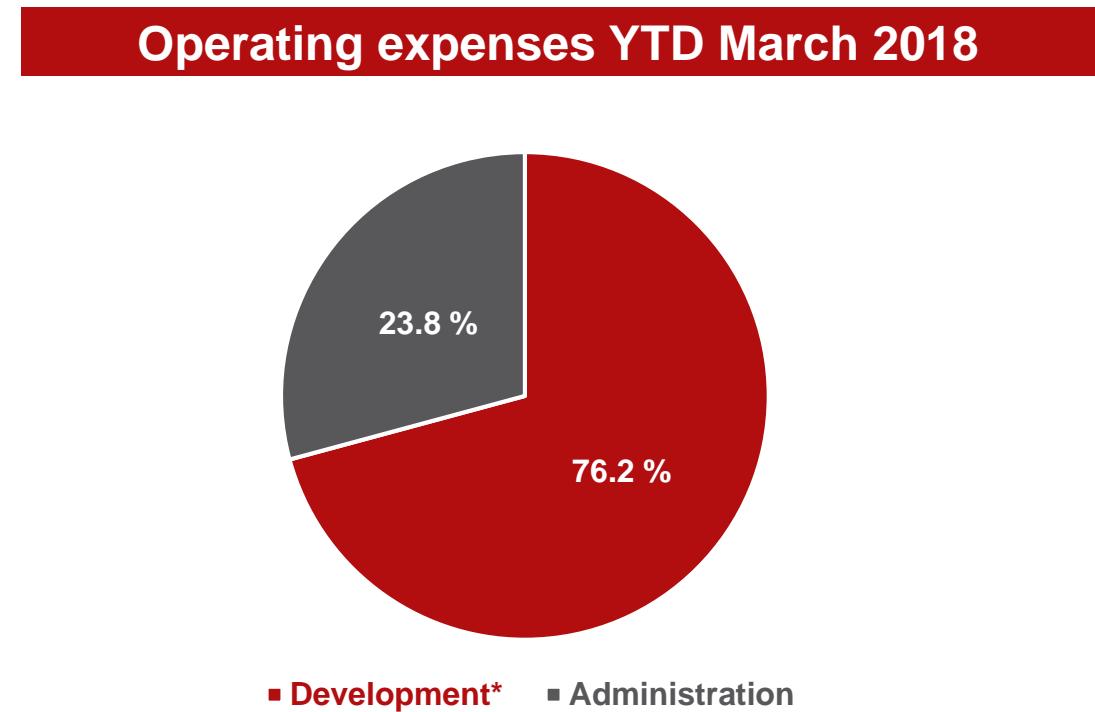
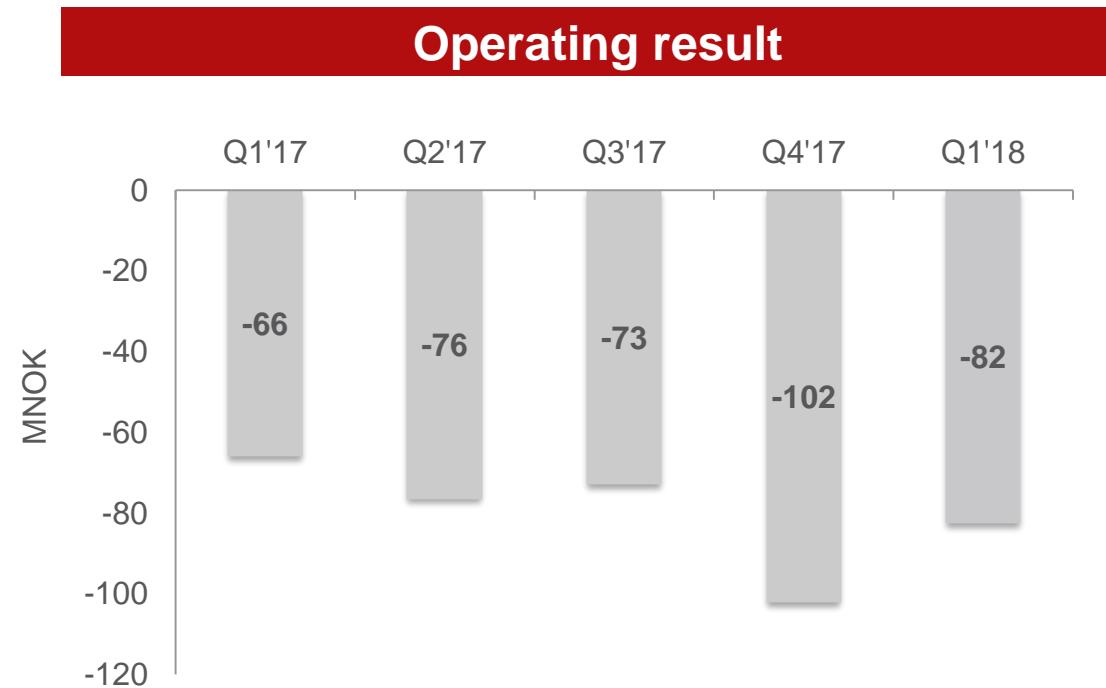
## FINANCIALS AND SUMMARY

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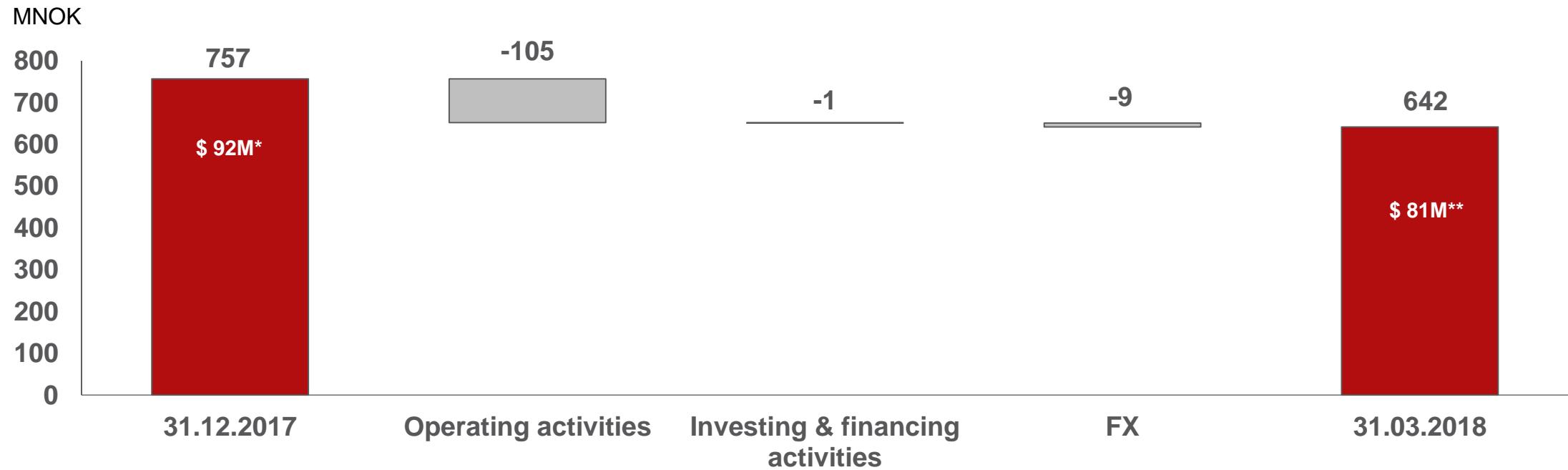


# Majority of resources allocated to PARADIGME



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

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



# Key company goals for 2018-2020

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

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\* Pending approval from regulatory authorities

# 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**

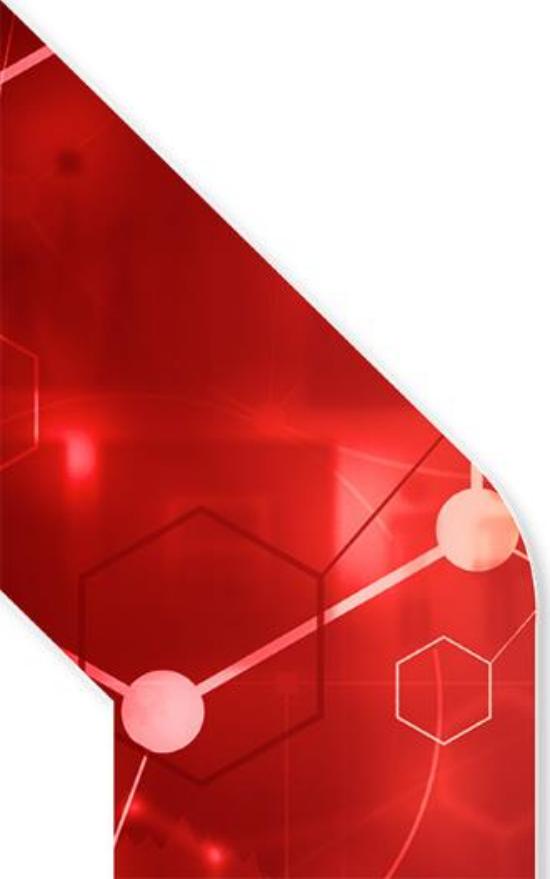
**November 21<sup>st</sup>, 2018**

**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 [ir@nordicnanovector.com](mailto:ir@nordicnanovector.com)



## Questions

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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 Lymphoma

**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 liilotomab

**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

**Satetrapetan:** 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