



AUGUST 22<sup>ND</sup>, 2019

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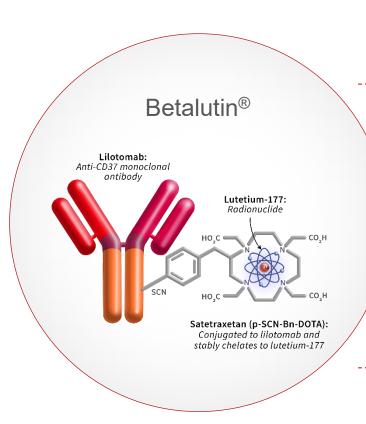
### Forward-looking statements

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Fully owned lead asset – a novel anti-CD37 radioimmunotherapy targeting unmet needs in the two largest NHL types – FL and DLBCL – a near USD 5B\* opportunity

A single administration of Betalutin<sup>®</sup> has demonstrated promising efficacy and safety in a 74-patient trial

Pivotal trial in 3L R/R FL underway with full enrolment expected 2H 2020; Fast-Track and Orphan Drug designations granted in US

On-going clinical programmes to access higher-value 2L FL and R/R DLBCL provide additional near-term value inflection points

R&D expertise and IP provides multiple opportunities in B-cell malignancies



## Nordic Nanovector pipeline – Multiple attractive opportunities in NHL



Candidate	Targeted indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Betalutin <sup>®</sup>	3L FL	PARADIGME –	Pivotal Phase 2b			
Betalutin <sup>®</sup> (combination w/RTX)	2L FL	Archer-1 – Phas	e 1b			
Betalutin <sup>®</sup>	R/R DLBCL (SCT ineligible)	LYMRIT 37-05 -	- Phase 1			
Humalutin <sup>®</sup> *	NHL	IND-ready				
<sup>212</sup> Pb-NNV003 (anti-CD37 radioimmunoconjugate)**	CLL and other NHL oranomed	R&D				
NNV014 (anti-CD37 ADC) (R&D collaboration)	CLL and other NHL	R&D				



## Highlights

- Preliminary analysis shows median duration of response (mDoR) of 13.5 months (formerly 9.0 months in December 2018) for Phase 1/2a LYMRIT 37-01 trial of Betalutin<sup>®</sup> in R/R FL
- Pivotal Phase 2b PARADIGME trial of Betalutin<sup>®</sup> in 3L FL progressing
  - 81 sites in 23 countries open for enrolment, as of Aug 21st, 2019
  - Recruitment has accelerated in recent months but not at the rate anticipated; full enrolment now expected 2H 2020 (vs 1H 2020)
- Phase 1b Archer-1 trial of Betalutin® plus RTX in R/R 2L FL advanced into second cohort
- Global patent portfolio strengthened with grant of European patent covering the use of Betalutin® (and other anti-CD37 targeting agents) in combination with anti-CD20 antibodies for the treatment of NHL
- Promising preclinical results from R&D collaboration to develop a novel CD37-targeting alpha therapy for B-cell tumours presented at international scientific congresses (TAT11 and TRP19)\*
- Recruitment completed for dose escalation phase of LYMRIT 37-05 trial of Betalutin®
  - Preliminary results from the dose-escalation phase expected in 2H 2019, expansion phase with selected best dose planned
- Dr Lars Nieba appointed Chief Technology Officer (20 year's experience from Bayer and Roche)





BETALUTIN® CLINICAL DEVELOPMENT IN 3L R/R FL





## Clinical development optimized to deliver Betalutin® to FL patients as soon as possible



 Objective is to deliver a product with a differentiated target product profile that meets the requirements of both regulatory and reimbursement agencies

#### LYMRIT 37-01 Phase 1/2a trial

Phase 1

Dose-escalation cohorts to determine the MTD/RDE\* of Betalutin®

Phase 2a

Dose expansion cohorts for confirmatory safety and exploratory efficacy

74 R/R iNHL patients with a median of 3 prior therapies

All patients received a single administration of Betalutin®

## PARADIGME Pivotal, global randomised Phase 2b trial

Comparing two dosing regimens with the goal to select the best Betalutin® dosing regimen for filing

3L FL patients refractory to anti-CD20 therapy

Target is 130 patients at 80-85 sites in approx. 20 countries
Primary endpoint: ORR
Secondary endpoints: DoR, PFS, OS, Safety, QoL

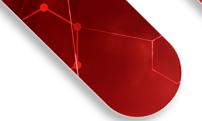
Complete patient enrolment in 2H 2020

US Filing

Betalutin® + RTX: Accelerate access to 2L FL through confirmatory Phase 3 trial



### LYMRIT 37-01: Promising safety and efficacy in R/R FL\*



#### **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 pts (19%)
- No cases of febrile neutropenia, low incidence of platelet transfusion, and no study related deaths

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

	ORR	CR
All patients (n=74)	61%	28%
All FL patients (n=57)	65%	28%
Arm 1 (40/15) (n=25)	64%	32%
Arm 4 (100/20) (n=16)	69%	25%
FL with ≥2 prior therapies (n=37)	70%	32%
RTX*-refractory FL, ≥2 prior therapies (n=21)	62%	19%
MZL (n=9)	78%	44%

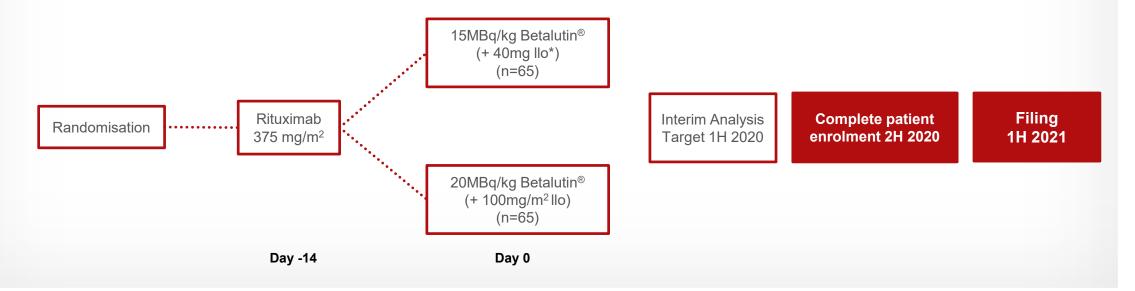
#### **Preliminary mDoR (Updated August 2019)**

- Preliminary analysis shows median duration of response (mDoR) of 13.5 months (formerly 9.0 months in December 2018). Final data will be presented at the R&D Day.
- Follow-up for mDoR is ongoing



### PARADIGME: Dose selection aligned with regulatory feedback

- Patient population: 130 patients with 3L FL who are refractory to anti-CD20 therapy
- Primary endpoint: Overall response rate (ORR)
- Secondary endpoints: Duration of response (DoR), Progression free survival (PFS), Overall survival (OS), Quality of life (QoL)



- 81 clinical sites are open for enrolment (as of Aug 21<sup>st</sup>, 2019)
- An interim analysis for futility is targeted for 1H 2020





- NOK 225m (gross) raised (Q1 2019) primarily for manufacturing development activities for Betalutin<sup>®</sup> and to begin scale-up of precommercialisation activities
- Betalutin<sup>®</sup> manufactured at the Institute for Energy Technology (IFE; Kjeller, Norway)
- Strong internal capabilities overseeing manufacturing, quality and distribution
- CMC (Chemistry, Manufacturing and Controls) strategy and documentation forms critical component of BLA filing











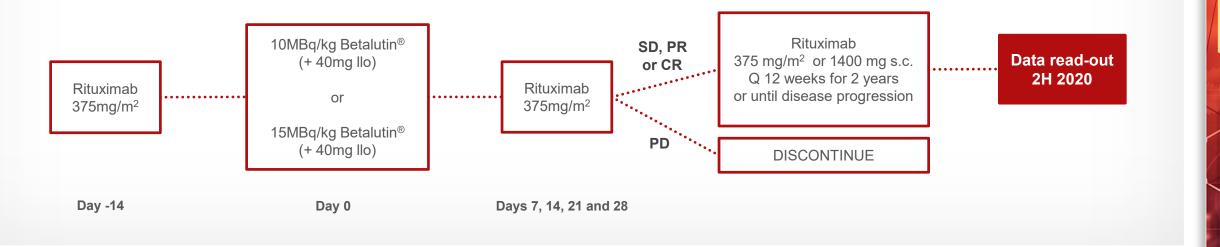






#### Archer-1: Betalutin® + rituximab in R/R FL

- Patient population: 20-25 patients with FL (grade I-IIIA) ≥1 prior regimens
- **Primary objective**: To evaluate the safety and tolerability of Betalutin® in combination with RTX
- Secondary objective: To evaluate the preliminary anti-tumour activity of combination treatment



- First patient dosed in November 2018
- First safety cohort completed (10 MBq/kg Betalutin®), dose increased (15 MBq/kg) for next 3-6 patients



# LYMRIT 37-05: Phase 1 dose-escalation study in R/R DLBCL patients not eligible for SCT



- **Patient population:** Up to 24 patients with R/R DLBCL **Primary objective**: Determine maximum tolerated dose (MTD) **Secondary objectives**: Safety and preliminary activity 20MBg/kg Betalutin®  $(+ 100 \text{ mg/m}^2 \text{ llo})$ (n ≥3) 15MBg/kg Betalutin® Initial data read-**Expansion Phase**  $(+ 100 \text{ mg/m}^2 \text{ llo})$ out with selected dose (n ≥3) 2H 2019 20 patients 10MBq/kg Betalutin® 10MBq/kg Betalutin® (+ 60 mg/m<sup>2</sup> llo) + 100 mg/m<sup>2</sup> llo (n ≥3) (n ≥3) \*all patients to receive RTX 375 mg/m2 on day -14
  - No safety issues were identified in the first 3 cohorts
  - Patient enrolment completed (July 2019)





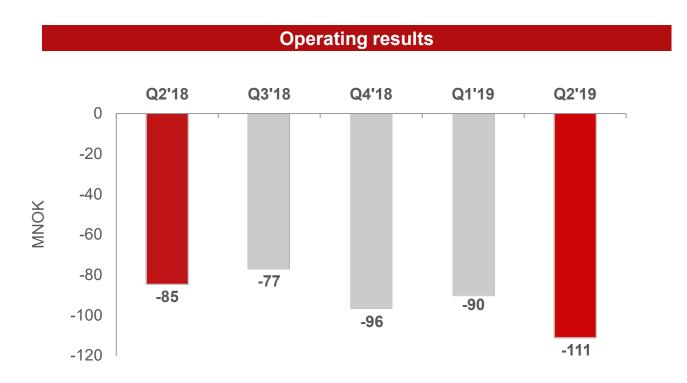
FINANCIAL RESULTS FOR Q2 AND 1H 2019



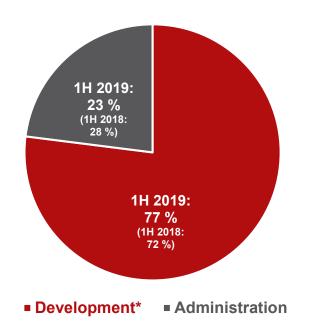


## Tight cost control; investment focused on clinical development and CMC activities





#### **Distribution of total operating expenses**

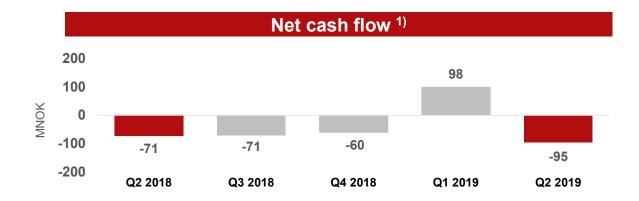


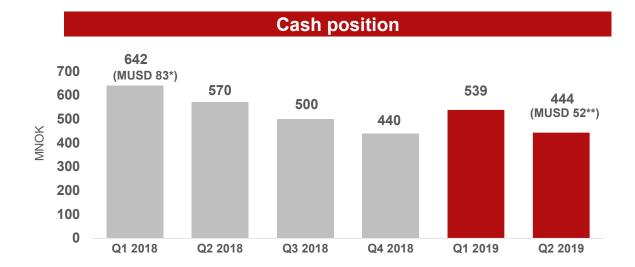


<sup>\*</sup> preclinical, clinical, medical affairs, regulatory and CMC activites

#### Cash resources through to mid-2020







#### Q2 2019:

- Net cash from operating activities of negative NOK 102.2 million
- Net cash flow from investing activities of NOK 0.2 million
- Net cash flow from financing activities of NOK 7 million
- Cash position of NOK 444 million as at end Q2 2019
- The company maintains its guidance that current cash resources are expected to be sufficient to reach mid-2020



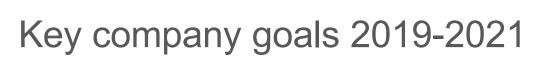
<sup>\*</sup> USD/NOK 7.75

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

### Strategic priorities focused on creating shareholder value

- Complete enrolment into PARADIGME to enable BLA\* filing for Betalutin® with differentiated product profile
- Advance clinical development of Betalutin® + RTX combination in 2L FL
- Progress clinical development plan with Betalutin® in DLBCL
- Develop and execute commercialisation strategy for Betalutin® in NHL in the US
- Opportunistically consider partnerships to further enhance shareholder returns
- Selectively extend pipeline targeting other B-cell malignancies leveraging radioimmunotherapy expertise
- Maintain rigorous capital management





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1H 2019	Betalutin <sup>®</sup> in DLBCL	LYMRIT 37-05: Enrolment completed (11 July)		
2H 2019	Betalutin <sup>®</sup> in DLBCL	LYMRIT 37-05: Data read-out		
1H 2020	Betalutin <sup>®</sup> in DLBCL	LYMRIT 37-05: First patient dosed (Expansion cohort)		
	Betalutin® in 3L FL	PARADIGME: Interim analysis for futility		
	Betalutin® + rituximab in 2L FL	Archer-1: Enrolment completed		
2H 2020	Betalutin® + rituximab in 2L FL	Archer-1: Data read-out		
	Betalutin® in 3L FL	PARADIGME: Enrolment completed (data read-out to follow a few months later)		
1H 2021	Betalutin® in 3L FL	Regulatory filing		





#### Financial calendar

Oslo R&D Day (webcast)	September, 2019 – date to be announced
Oslo Q3 2019 results (webcast)	November 19 <sup>th</sup> , 2019

February 2020

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

Oslo Q4 2019 results (webcast)

- 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>





### Questions

