# **Q3 2018** INTERIM RESULTS AS OF SEPTEMBER 30, 2018



# FORWARD-LOOKING STATEMENTS

This presentation includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of our control that could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements regarding our short-term objectives and opportunities, financial expectations for the full year and financial preparedness as of year end, as well as statements concerning our plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. We undertake no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

# **RECENT HIGHLIGHTS**



#### MVA-BN (IMVAMUNE)

- BLA has been submitted to the FDA with anticipated approval and award of Priority Review Voucher in 2019
- Recent monkeypox cases in humans highlight need for stockpiling a non-replicating smallpox vaccine

#### RSV

• Discussions with FDA on regulatory pathway initiated

#### Cancer immunotherapy

- All three planned Phase 2 trials combining **CV301** and checkpoint inhibitors are now initiated
- Pivotal registration trial of BN-Brachyury initiated in chordoma

#### **Financials**

• On track to meet full year guidance



#### BAVARIAN NORDIC

# **MVA-BN SMALLPOX VACCINE**

- The BLA for liquid-frozen MVA-BN has been submitted to FDA
- Review will start upon acceptance of the BLA, which is expected before year-end
- Approval, if granted, is anticipated in 2019
- If approved, the Company would also be eligible to receive a Priority Review Voucher





# **MONKEYPOX - A NEED FOR VACCINES?**

- Recent cases of human monkeypox in the U.K. and Israel highlight the need for preparedness plans and update of stockpiles with safest alternatives
- Since 2017, +100 human cases reported in Nigeria including multiple deaths
- 3 cases in U.K. and 1 in Israel, all related to current Nigeria outbreak
- U.K. authorities chose IMVANEX\* over currently stockpiled, replicating smallpox vaccines for vaccination of healthcare workers

#### Monkeypox

- Zoonotic disease (transmission from animals to humans), with mortality rate ranging from 1-10%
- Human-to-human
  transmission
- No approved vaccines, but smallpox vaccines historically showed efficacy in preventing monkeypox

# FREEZE-DRIED MVA-BN CONTRACT WITH USG TIMELINES AND REVENUES





**Bulk vaccine** 



Construction of fill/finish plant



Freeze-dried MVA-BN

#### **BAVARIAN NORDIC**

# OUR COLLABORATION WITH JANSSEN A LONG-TERM VALUE DRIVER



#### 4 license agreements in place

- The combination of Janssen's AdVac + MVA-BN has demonstrated robust and sustained immune responses in people
- The synergistic benefit of combining our technology has been key to establishing collaborations in blockbuster indications
- Equity investments have made JNJ a major shareholder with ownership of 5.77%



#### The vaccine is mimicking a natural response to an RSV infection that is believed to induce protection for at least a year.

#### **Competitive Advantages**

- Induction of a broad T-cell and antibody response against RSV
- Induction of mucosal immunity
- Durable immune response lasting longer than an RSV season
- Based on MVA-BN live virus adjuvant with a favorable safety profile

# AT THE FOREFRONT OF RSV VACCINE DEVELOPMENT

# Novel Vaccine Design

• Encodes 5 distinct targets of RSV to stimulate a broad protective immune response (T-cell and antibody response).

F<sub>(A)</sub> G<sub>(A)</sub> G<sub>(B)</sub> Ν M2

**MVA-BN RSV** 

### MVA-BN RSV PHASE 2 BOOSTER STUDY SUMMARY

- Broad RSV antibody response remained elevated in at least 60% of the subjects 1 year post a single vaccination
- An annual booster induced a broad and robust immune response
  - Rapid increases of neutralizing and total antibodies against both RSV subtypes
  - Increases in mucosal RSV specific IgA (correlate of protection)
  - Broad, robust, and cellular immune response to all 5 RSV proteins
  - Effect was most notable in subjects with the weakest immunity prior to the annual booster vaccination
- Findings support an annual vaccination strategy with MVA-BN RSV



# **MVA-BN RSV**



#### Status and next steps

- A feasibility assessment of performing a human challenge study using a potentially more virulent RSV isolate to generate initial efficacy data for MVA-BN RSV was conducted
- We have not been able to confirm the feasibility of manufacturing a more virulent RSV isolate and have concluded that such a study would not be practical or assist in the planning of a Phase 3 trial
- Discussions with FDA on regulatory pathway have been initiated and will continue into 2019



# IMMUNO-ONCOLOGY STRATEGY OFFERING WIDE OPPORTUNITIES TO TRANSFORM THE TREATMENT LANDSCAPE

- Innovative immuno-oncology candidates targeting solid tumors
- Enhanced dosing regimen to drive powerful priming and activation
- Prime-boost vaccine regimen to create a robust T-cell response
- Improved antigen selection to induce tumor specific Tcells
- Combined with checkpoint inhibitors to increase infiltration and killing of tumor cells
- Developing next-generation intra-tumoral and intravenous administrations
- Working with **adaptive trial designs** to seek capitalefficient, rapid proof of concepts



# **BRACHYURY** - NEW FRONTIERS IN TREATING METASTATIC CANCERS

- BN-Brachyury candidate utilizes a prime-boost vaccination regimen that has been optimized to include the gene for brachyury and other molecules known to increase immune activation
- Phase 1 data demonstrated that BN-Brachyury can safely target brachyury and induce brachyury-specific T-cell immune responses
- Recently initiated Phase 2 trial in chordoma
- Received orphan drug status from the FDA
- Potential for Breakthrough Designation

#### Brachyury

- Tumor-associated antigen that is overexpressed in major solid tumor indications and several ultra-rare orphan cancers
- Expression is highly correlated with metastatic disease, multi-drug resistance and decreased survival rates

## **PIVOTAL TRIAL ONGOING IN CHORDOMA** ULTRA-ORPHAN CANCER WITH LIMITED TREATMENT OPTIONS

- Multi-site trial to assess the effectiveness of **BN-Brachyury** and current standard of care, **radiation** therapy, in patients with **advanced chordoma**
- Radiation has been shown to inflame the tumor, releasing cancer antigens, increasing the targeting of brachyury
- Patients will receive a primer of MVA-BN Brachyury followed by a booster of the recombinant fowlpox virus FPV-Brachyury and radiation therapy
- Determine if combo therapy results in a clinicallymeaningful ORR

#### STAGE 1 (10 patients )

 Only proceed to stage 2 if at least 1 objective response occurs STAGE 2 (19 patients)

• ORR goal total = 4/29 patients

#### Chordoma

- Rare cancer that occurs in the skull base and spine that universally overexpresses brachyury
- 1,000 new cases in the U.S. and E.U. annually
- Historical objective response rate (ORR) with radiation alone <5%</li>

# **CV301** UNLEASHING CHECKPOINT INHIBITORS

- Cancer immunotherapy CV301 targets tumor-associated antigens, CEA and MUC1, which are overexpressed on numerous solid tumors
- Improved dosing administration in 4 different injection sites, vs. 1, to create a potent and durable T-cell response
- Strong preclinical evidence suggests promising combination synergies with checkpoint inhibitors
- CV301 was shown to induce tumor-specific T-cells that infiltrated the tumor, causing the upregulation of PD-L1
- The addition of CV301 to checkpoint inhibitors may provide benefit to the 70-75% of patients who do not respond to checkpoint inhibitors alone

#### CEA & MUC1

 Tumor-associated antigens, which are overexpressed on numerous solid tumors such as bladder, colorectal and pancreatic cancers

# **CV301** THREE PHASE 2 COMBINATION TRIALS ONGOING



Investigator sponsored studies and studies that employ adaptive trial designs to provide a capital-efficient, rapid proof of concept

#### **Bladder cancer**

CV301 + TECENTRIQ (atezolizumab)

Phase 2 initiated September 2018

Primary Endpoint: Objective Response Rate (ORR)

Bavarian Nordic-sponsored trial

#### **Colorectal cancer**

CV301 + OPDIVO (nivolumab) & chemotherapy

Phase 2 initiated July 2018

Primary Endpoint: Overall Survival (OS)

Sponsored by Rutgers University Colorectal & Pancreatic

CV301 + IMFINZI (durvalumab)

Phase 2 initiated November 2018

Primary Endpoint: Progression Free Survival (PFS)

Sponsored by Georgetown University

# INTRA-TUMORAL AND INTRAVENOUS ADMINISTRATION

# Strengthening our Immuno-oncology platform

Developing intra-tumoral (IT) and intravenous (IV) administration of cancer immunotherapies as a potent approach to activate both arms of the immune system and alter the suppressive tumor microenvironment (TME)

#### Preclinical data of IT and IV immunotherapy demonstrate:

- Strong activation of innate and adaptive immune mechanisms
- Inflammatory responses in the TME
- Tumor-specific T cell recruitment into the tumor tissue
- Control of tumor growth
- Synergies with immune checkpoint blockade

# **INTRAVENOUS**



#### Benefits of IV administration:

- Improved quantity of T-cell response
- Stimulates NK cell activation and expansion to recognize cancer cells and overcome MHC loss
- Induces systemic cytokine responses
- Elevated responses when vaccine also encodes CD40L
- Phase 1 planned with BN-Brachyury in 1H19



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# **INTRA-TUMORAL**



#### **Benefits of IT administration:**

- 'Heats' up the TME by generating intra-tumoral inflammation
- Creates a systemic immune response by activating tumor-antigen specific CD8 T cells
- Phase 1 trial planned with CV301 in 1H19



Delayed tumor growth in model with intratumoral administration of MVA

# FINANCIAL RESULTS AND OUTLOOK

#### On track to meet full year guidance

- Q3 revenues high as expected (DKK 222 million) and for Q4, all vaccine has already been produced and invoiced as of the reporting date
- A total of 350 mDKK will be invoiced for MVA-BN in 2018, including RoW contracts; other revenue of 150 mDKK relates to already signed R&D contracts

# ce Revenue 9m, 2018



MVA-BN, US + RoW R&D Contracts

		mDKK		mUSD	
	9m 2018	FY2018E	9m 2018	FY 2018E	
Revenue	319	500	50	78	
EBIT	(261)	(385)	(41)	(60)	
Cash preparedness	2,401*	2,100	373	326	

Cash preparedness includes cash, cash equivalents, investments in securities and the aggregate amount of undrawn credit lines.

\* DKK 249 million deducted by loans related to repo transactions

# **FINANCIAL POSITION**



#### Break-down of financial position

- Strong financial position enabling continued execution of strategy
- Cash preparedness of DKK 2,401M including unutilized credit lines

		mDKK		mUSD	
	9m 2018	FY2017	9m 2018	FY 2017	
Securities, cash & equivalents	2,407	2,584	374	401	
Less Repo assets	-249	-	-39	-	
Unutilized credit lines	243	20	38	3	
Total cash preparedness	2,401	2,604	373	404	
Mortgage	28	30	4	5	
EIB loan	372	372	58	58	
Total debt (excl Repo liability)	400	402	62	63	

USD/DKK = 6.44

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# ANTICIPATED SELECTED MILESTONES

#### MVA-BN smallpox vaccine

- FDA acceptance of the Biologics License Application (BLA) for liquid-frozen MVA-BN (Q4, 2018)
- Initiate Phase 3 MVA-BN freeze-dried lot consistency study (H1, 2019)
- Anticipated FDA approval (2019)
- Award of a Priority Review Voucher (2019)

#### RSV

- Continue discussions with the FDA on the regulatory pathway for approval (H1, 2019)
- Initiate Phase 3 study (2020)

### JANSSEN

- Initiate Phase 1/2a study of MVA-BN HPV+AdVac (Q4, 2018\*)
- Initiate Phase 1 study of MVA-BN HIV+AdVac (Q4, 2018\*)

### CV301

- Results from Phase 1/1b NSCLC combination (Q4, 2018)
- Initiate a Phase 1 intra-tumoral administration in patients with solid tumors (H1, 2019)

#### BRACHYURY

- Results from Phase 1 study (Q4, 2018)
- Initiate Phase 1 intravenous administration (H1, 2019)
- Results from Phase 2 study in chordoma (H2, 2019)

<sup>\*</sup> Janssen is responsible for the clinical development



