THE FUTURE OF VACCINES

JYSKE BANK SELSKABSDAG

NOVEMBER 24, 2016
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.
# Strong Foundation for Further Development

**Prostvac**
- Prostate cancer
- Partnered with Bristol-Myers Squibb
- Phase 3 fully enrolled
- Phase 3 top-line data expected in 2017
- Multiple clinical studies being advanced in earlier stages and in combination regimens

**IMVAMUNE**
- Smallpox vaccine
- Approved in EU & Canada
- 28 million doses delivered to US
- $233 million in bulk vaccine orders bridging to next-generation freeze-dried vaccine
- Recurrent orders from Canada

**Janssen**
- Partnership
- 2 license agreements in Ebola & HPV
- Moved Ebola vaccine from preclinical to Phase 3 in 9 months
- 2 million doses of Ebola vaccines produced

**Pipeline**
- Projects
- Advancing clinical development of RSV vaccine in elderly & children
- Advancing development of CV-301 in combination treatment for multiple cancers
- Supporting NCI in clinical development of MVA-BN Brachyury
LIVE VIRUS VACCINE PLATFORM
VALIDATED AND MODULAR APPROACH EMPLOYING POXVIRUSES

Antigenic Complexity

- Low
  - Wide Variety of Target Diseases
- High
  - Recombinant Poxviruses

Recombinant Poxviruses

- Simple
  - Target Multiple Antigens for a Single Disease
- Complex
  - Customized Immunogenicity

Vectors  Antigens  Promoters  Co-Stimulatory Molecules (TRICOM)

Widely Applicable Technology for Infectious Disease and Cancer Immunotherapy
## PIPELINE

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<th>INDICATION</th>
<th>ONGOING STUDIES</th>
<th>PRECLINICAL</th>
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<td>IMVAMUNE liquid-frozen ¹)</td>
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<td>Janssen</td>
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<td>Chronic HPV Infection</td>
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<td><strong>CANCER IMMUNOTHERAPY</strong></td>
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<td>PROSTVAC</td>
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<td>Bristol-Myers Squibb</td>
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<td>CV301</td>
<td>Lung Cancer (NSCLC)</td>
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<tr>
<td>MVA-BN Brachyury</td>
<td>Metastatic Tumors</td>
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<td></td>
<td>Bavarian Nordic</td>
<td></td>
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</table>

1) Approved in the European Union under the trade name IMVANEX® and in Canada under the trade name IMVAMUNE®. Phase 3 registration studies are ongoing in the United States.
COMMERCIAL MANUFACTURING CAPABILITIES

Commercial Production Facility
• Inspected by the EMA and the FDA
• 28M doses of IMVAMUNE delivered to US national stockpile
• Over 2M doses of MVA-BN Filo (Ebola) delivered to Janssen

Poxvirus Manufacturing Expertise
• Commercial partnerships in place with Janssen & BMS
• All manufacturing performed by BN
• Company has developed IP and extensive know-how in the production of poxvirus based vaccines

Multi-Product Facility
• Highly scalable, fully integrated, reduces dependency on sub-contractors
• Fill/Finish established to support commercial launch of PROSTVAC
• Production of all clinical trial material
IMVAMUNE PARTNERSHIP WITH THE U.S.

More than $1.2bn in R&D and supply contracts to-date

IMVAMUNE® liquid-frozen
- R&D & Supply Contracts
  - 20 million doses
  - $679m
  - 2003 - 2012

IMVAMUNE® freeze-dried
- R&D Contract
  - $95m
  - 2009-2011

- Bulk Supply
  - $233m
  - 2015-2016

Stockpile Resupply
- 20 million doses
- 2013

- 132 million doses
- 2015-2020

Long-term stockpiling goal

More than $1.2bn in R&D and supply contracts to-date
OUR COLLABORATION WITH JANSSEN

MVA-BN Filo (Ebola)
License & Supply Agreement
US$ 187m

2014

MVA-BN HPV
License Agreement
US$ 171m

2015

MVA-BN
Undisclosed target
Potential license agreement

MVA-BN
Undisclosed target
Potential license agreement

A sustained partnership

- Janssen took almost 5% equity stake in BN upon signing Ebola deal
- Validation of our MVA-BN technology & manufacturing
- Recent publication of Ebola Phase 1 data confirms durable immune responses when combining MVA-BN and AdVac.
Large unmet medical need: children & elderly

- Global RSV disease burden is estimated at 64 million cases and 160,000 deaths every year
- The U.S. Centers for Disease Control and Prevention (CDC) reports that each year the disease causes 177,000 hospitalizations and 14,000 deaths among adults older than 65
- No approved prophylactic vaccine available
• Based upon the MVA-BN vaccine vector - favorable safety profile, approved in EU & Canada and commercial manufacturing in-place
• Designed to generate a balanced antibody and T cells responses to both RSV subtypes (A&B)
  • Encodes two main surface proteins F & G
  • Encodes the G surface protein from both RSV subtype A&B - poor cross reactivity between RSV subtypes
  • Encodes two highly conserved internal RSV proteins (N & M2) - good inducers of T cell responses

Construct was designed for a balanced immune response to minimize the risk of enhanced disease & encourage cross strain reactivity (protection against both RSV subtypes)
MVA-BN-RSV INDUCES A BALANCED IMMUNE RESPONSE SIMILAR TO A NATURAL RSV INFECTION

**Total anti-RSV antibodies**

- **RSV**
- **MVA-BN-RSV**
- **FI-RSV**

**RSV neutralizing antibodies**

- **RSV**
- **MVA-BN-RSV**
- **FI-RSV**

**T cell responses**

- **M2 peptide**
- **G peptide**
- **F peptide**
RSV PHASE 1 POSITIVE TOP LINE RESULTS

Randomized, placebo controlled study, 63 healthy subjects

Safety

• No unexpected and/or serious adverse reactions

• Vast majority of events represent local and systemic reactions typical for vaccines - reported as mild to moderate and resolved rapidly without intervention (≤5 days)

• Low incidence of local and systemic reactions typical for vaccines and comparable between age groups

Immunogenicity

• Dose response and differences between age groups was observed in the immune responses

• Antibodies against RSV significantly boosted in the majority of subjects
  • 2-fold increase in both IgG and IgA in elderly
  • Boosted neutralizing antibodies against both RSV subtypes (A&B)

• T cell responses were boosted in all elderly subjects
  • 3-5 fold increase in T cell responses (F, G, N proteins & whole RSV)
  • Robust T cell response
Randomized, blinded, placebo-controlled dose ranging study

- 400 healthy subjects (≥55 years old)
- Study will help identify optimal dose and schedule
- Top-line data available mid-2017
- Subsequent Phase 2b field efficacy study planned for later 2017
- Also exploring pediatric population

### MVA-BN RSV PHASE 2 DOSE RANGING STUDY

<table>
<thead>
<tr>
<th>Groups</th>
<th>N</th>
<th>Vaccine Dose</th>
<th>Schedule (Day)</th>
<th>Route</th>
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<tbody>
<tr>
<td>1</td>
<td>80</td>
<td>Low</td>
<td>MVA-BN RSV</td>
<td>Placebo</td>
</tr>
<tr>
<td>2</td>
<td>80</td>
<td>Low</td>
<td>MVA-BN RSV</td>
<td>MVA-BN RSV</td>
</tr>
<tr>
<td>3</td>
<td>80</td>
<td>High</td>
<td>MVA-BN RSV</td>
<td>Placebo</td>
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<tr>
<td>4</td>
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<td>MVA-BN RSV</td>
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<tr>
<td>5</td>
<td>80</td>
<td>-</td>
<td>Placebo</td>
<td>Placebo</td>
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<tr>
<td>Total</td>
<td>400</td>
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</table>
PROSTVAC CANCER IMMUNOTHERAPY
PHASE 3 STUDY STATUS

PROSPECT
A Randomized, Double-blind, Global Phase 3 Efficacy Trial of PROSTVAC in Metastatic Castration-Resistant Prostate Cancer

Randomization by region (N=1,297)

- **25.7%** Rest of World (n=333)
- **38.2%** Western Europe (n=497)
- **18.4%** North America Oncology (n=239)
- **17.7%** North America Urology (n=229)
- **17.7%** USA, Canada

Final data anticipated in 2017

<table>
<thead>
<tr>
<th>Analysis</th>
<th>Events</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Interim Analysis #1</td>
<td>214 events</td>
<td>40%</td>
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<tr>
<td>Interim Analysis #2</td>
<td>321 events</td>
<td>60%</td>
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<tr>
<td>Interim Analysis #3</td>
<td>427 events</td>
<td>80%</td>
</tr>
<tr>
<td>Final Analysis</td>
<td>534 events</td>
<td>100%</td>
</tr>
</tbody>
</table>

Injections

- Average was **6.1 injections**
  
- Randomized Phase 2 trial (n=122) had average of **5.4 injections**

- An increased number of injections is expected to improve the clinical outcome for patients receiving the active drug.

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1) Subjects who have completed study treatment phase or have completed 7th dosing visit. N=1,279
2) Kantoff et al., Journal of Clinical Oncology, January 2010
## PROSTVAC COMMERCIAL LICENSE WITH BMS

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Value</th>
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<tbody>
<tr>
<td>Upfront payment</td>
<td>$60M</td>
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<tr>
<td>License</td>
<td>$80M</td>
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<tr>
<td>Phase 3 data</td>
<td>$50M</td>
</tr>
<tr>
<td>Data-driven milestones</td>
<td>$180M*</td>
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<tr>
<td>Regulatory milestones</td>
<td>$110M</td>
</tr>
<tr>
<td>Sales milestones</td>
<td>$495M</td>
</tr>
<tr>
<td>Tiered royalties on future sales</td>
<td>High teens up to mid-twenties</td>
</tr>
</tbody>
</table>

* Based on Phase 2 data
PROSTVAC STUDIES
SPAN PROSTATE CANCER DISEASE LANDSCAPE

Hormone dependent
Nonmetastatic

Castration resistant
Metastatic

No pain

Pain

Tumor volume

chemotherapy, radiation therapy

depth

chemotherapy, immunotherapy

chemotherapy

hormonal

hormonal, immunotherapy

mono (NCI)

mono (NCI)

mono (NCI)

ipi combo (NCI)

mono (NCI)

mono (NCI)

radiation combo (NCI)

ipi combo (UCSF)

ipi + nivo combo (NCI)

mono (MUSC)

surgery

mono (NCI)

hormonal combo (NCI)

hormonal combo (NCI)

hormonal combo (NCI)

Phase 3 (BN)

chemotherapy combo (NCI)

mono (NCI)

mono (NCI)

mono (NCI)

chemotherapy, mono (NCI)

chemotherapy, mono (NCI)

chemotherapy, mono (NCI)

chemotherapy, mono (NCI)

chemotherapy, mono (TB)

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chemotherapy, mono (NCI)
PROSTVAC - PATIENT CASE HISTORY ("FRANK")
PUBLISHED 2013 CASE REPORT IN *CLINICAL GENITOURINARY CANCER*

Gleason grade: 4 + 3 = 7

- Trend before radical prostatectomy
- Trend after radical prostatectomy. External beam radiation
- Trend after first vaccine trial
- Trend after second vaccine trial

- 5.8 months DT (doubling time)
- 9.6 months DT
- 28.6 months DT
DEMONSTRATED POTENTIAL AS A COMBINATION THERAPY WITH BMS’ IPILIMUMAB

PROSTVAC + ipilimumab Phase 1 Trial

Additional Phase 2 Combination Studies

Neoadjuvant Prostate cancer

Patients in 10mg/kg dose cohort (N=15) reported 37.2 months median overall survival. ~20% of 10mg/kg patients remain alive at 80 months

CV301 CANCER IMMUNOTHERAPY
DESIGNED FOR THE TREATMENT OF MULTIPLE CANCERS

Developing CV301 in combination with checkpoint inhibitors

• Proof-of-concept studies of CV301 plus PD-1/PD-L1 being explored in company collaborations or with NCI
• NSCLC targeted as first indication in BN sponsored trial
• Additional indications under evaluation

New and improved construct leverages existing clinical data

• Preliminary evidence of efficacy generated in multiple clinical studies
• Safety data with over 300 subjects treated

\[ \text{MVA-BN} + \text{CEA} + \text{MUC-1} = \text{CV301} \]

Lung, Breast, Colorectal, Ovarian, Gastric, Bladder, Liver and Renal cancer
PHASE 2 CV301 & NIVOLUMAB COMBINATION IN NSCLC

**Phase 1**
Safety CV301 single agent (n=18)

Single dose combination with nivolumab (n=22)

**Phase 2**
Multi-center trial
Up to 20 sites in USA

Randomization
CV301 + nivo (n=60)  nivo (mono) (n=60)

**Endpoints**
- Safety, tolerability
- Primary endpoint: OS
- Secondary endpoints: ORR, DOR, PFS, Immune effects

- Second-line treatment, potential for first-line treatment
- BMS will supply nivolumab at no cost to BN
- Bavarian Nordic retains all commercial rights to CV301
**Indications**
- Chordoma (ultra-orphan disease)
- Triple negative breast cancer
- Merkel Cell Carcinoma
- NSCLC
- Multiple solid tumors

**Development Strategy**
- NCI Phase 1 and Phase 2 trials
- NCI Phase 2 chemotherapy combination trial(s)
- NCI erlotinib combination trial(s)
- NCI and BN immune checkpoint inhibitor combinations

- Brachyury expression is highly correlated with metastatic disease, and multi-drug resistance
- Brachyury is not expressed in most normal tissue
- Brachyury is responsible for epithelial to mesenchymal transition (EMT), which is a major driver of metastasis
These findings show for the first time that advanced cancer patients can be safely immunized with an MVA-based vaccine targeting brachyury, and can develop brachyury-specific T-cell immune responses.

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1Heery, Donahue, et al.
FINANCIAL PERFORMANCE

- Revenues of more than DKK 1bn for the fourth consecutive year
- Break-even result for third consecutive year
- Cash preparedness doubled since 2013
ANTICIPATED SELECTED MILESTONES
2016/2017

**IMVAMUNE**
- U.S. RFP for freeze-dried IMVAMUNE

**RSV**
- MVA-BN RSV Phase 2 dosing study read out
- MVA-BN RSV Phase 2 field efficacy initiation

**Janssen**
- Initiate HPV Phase 1 study in cervical cancer
- Potential expanded collaboration with Janssen on two additional infectious disease targets
- Data from Phase 2 and Phase 3 studies of the Ebola prime-boost vaccine regimen

**PROSTVAC**
- Phase 3 top-line data including interim analyses
- Data from NCI-sponsored Phase 2 trials
- Initiate NCI-sponsored Phase 2 study in combination with ipilimumab and nivolumab

**CV301**
- CV301 + nivolumab proof-of-concept study initiation in lung cancer
- CV301 + checkpoint inhibitor proof-of-concept studies in additional indications

**Brachyury**
- MVA-BN Brachyury Phase 2 initiation