

# ANNUAL REPORT 2016



BAVARIAN NORDIC



# 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.*

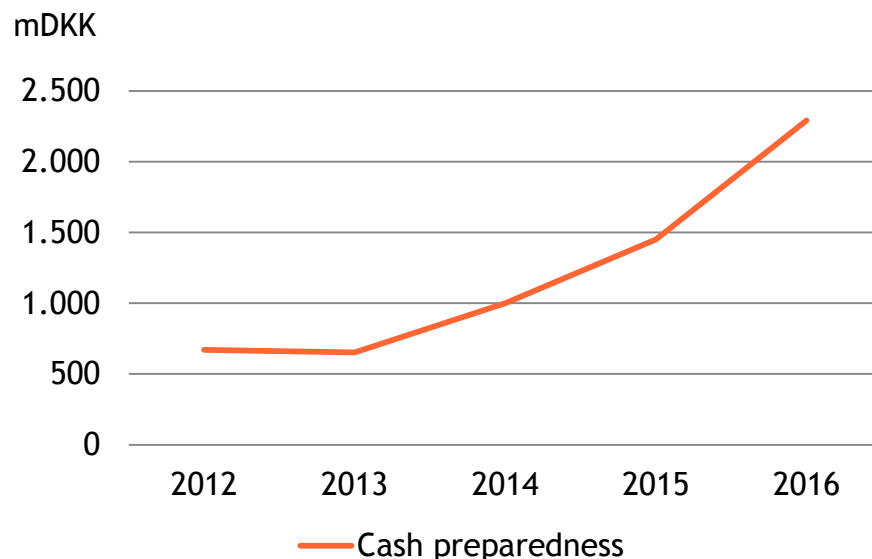
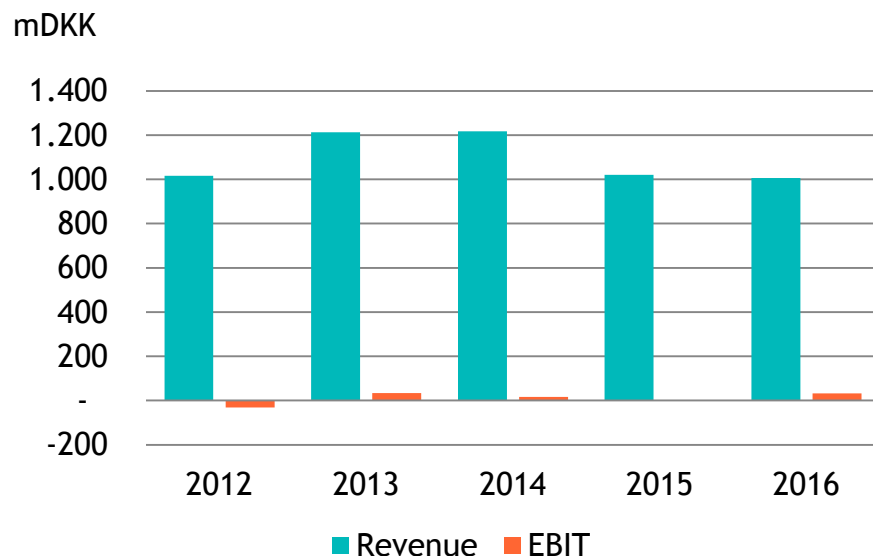


# FINANCIALS

OLE LARSEN, CFO

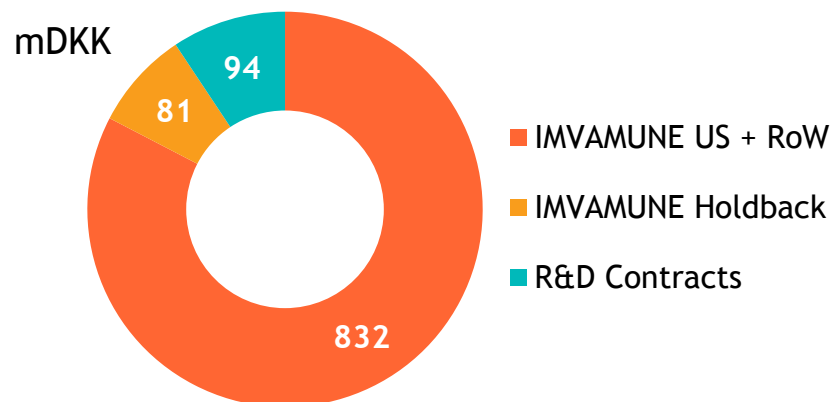
# WE MET OUR FINANCIAL GUIDANCE AND STRENGTHENED OUR CASH PREPAREDNESS

- Consistent with previous years we have generated revenues above DKK 1 billion and recorded a break-even result
- Cash preparedness was significantly strengthened and has more than tripled over the last three years

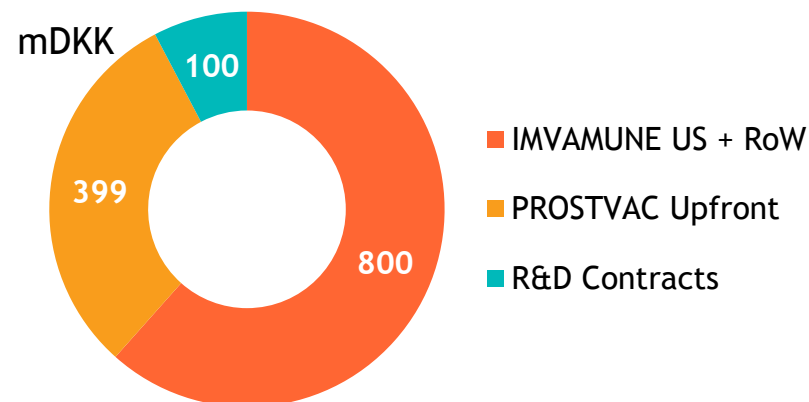


# FINANCIAL SUMMARY AND OUTLOOK

## Revenue 2016



## Revenue 2017



		2016		2017	mUSD		
		2016		2017			
mDKK	guidance	actual	guidance		guidance	actual	guidance
Revenue	1,000	1,007	1,300		142	143	184
EBIT	0	33	350		0	5	50
Cash preparedness at year-end	2,300	2,292	2,400		326	325	340

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



# **STRONG PIPELINE PROGRESS**

PAUL CHAPLIN, CEO AND PRESIDENT



# STRONG PROGRESS IN 2016 DRIVEN BY MULTIPLE LAYERS OF VALUE

- Expansion, advancement and diversification of pipeline
- Continued strong financial performance
- Significant pipeline news flow expected in 2017

## Key value drivers in 2017 and beyond

IMVAMUNE

PROSTVAC

CV301

MVA-BN RSV

### Existing & future partnerships



Bristol-Myers Squibb



# PREPARING FOR THE NEXT GENERATION OF IMVAMUNE SMALLPOX VACCINE

- Received new USD 100 million bulk order from the U.S. Government
- Completed enrollment of the final Phase 3 study of liquid-frozen formulation required prior to submission for U.S. approval
  - Data read out H2 2017
  - Submission of BLA in Q2 2018 with fast-track designation
  - Approval and receipt of Priority Review Voucher
- RFP process for freeze-dried IMVAMUNE is expected to start in 2017





# MOVING TOWARDS FINAL DATA FOR PROSTVAC

## ADDITIONAL COMBINATION STUDIES CONTINUES TO EXPAND POTENTIAL

- The first and second interim analyses of the Phase 3 study have been completed and the study continues as planned
- Interim #3 and final analysis expected before year-end
- Three new Phase 2 studies of PROSTVAC were initiated during the year
- Now 10 ongoing trials and additional trials are in the planning
- Data from combination studies are expected from 2017 and onwards

### PROSPECT Phase 3 Trial

A Randomized, Double-blind,  
Global Phase 3 Efficacy Trial of  
PROSTVAC in Metastatic Castration-  
Resistant Prostate Cancer (N=1,297)

Primary endpoint: Overall survival

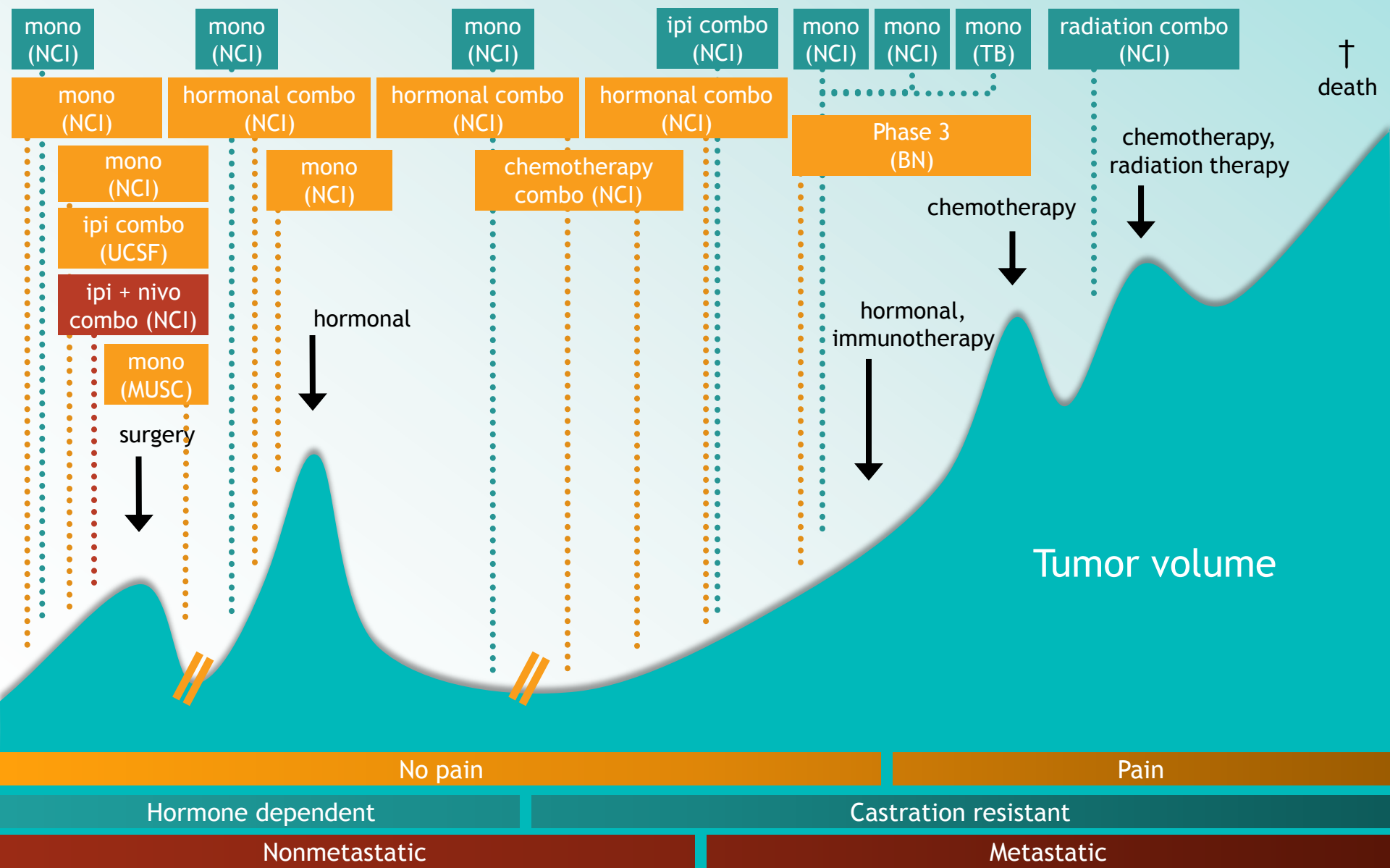
Interim Analysis #1	214 events	40%	✓
Interim Analysis #2	321 events	60%	✓
Interim Analysis #3	427 events	80%	Mid-2017
Final Analysis	534 events	100%	2H 2017

*Estimated timing of events*

# PROSTVAC STUDIES

## SPAN PROSTATE CANCER DISEASE LANDSCAPE

■ COMPLETED 
 ■ ONGOING 
 ■ PLANNED

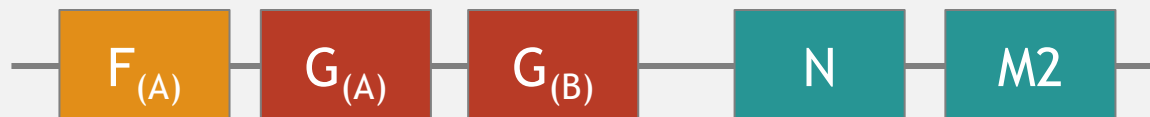


# RSV - A SIGNIFICANT OPPORTUNITY

- Reported promising Phase 1 data
- Completed enrollment of a Phase 2 study in 400 elderly subjects
- Results are expected in mid-2017 and will provide important information for larger efficacy studies
- Also exploring pediatric population

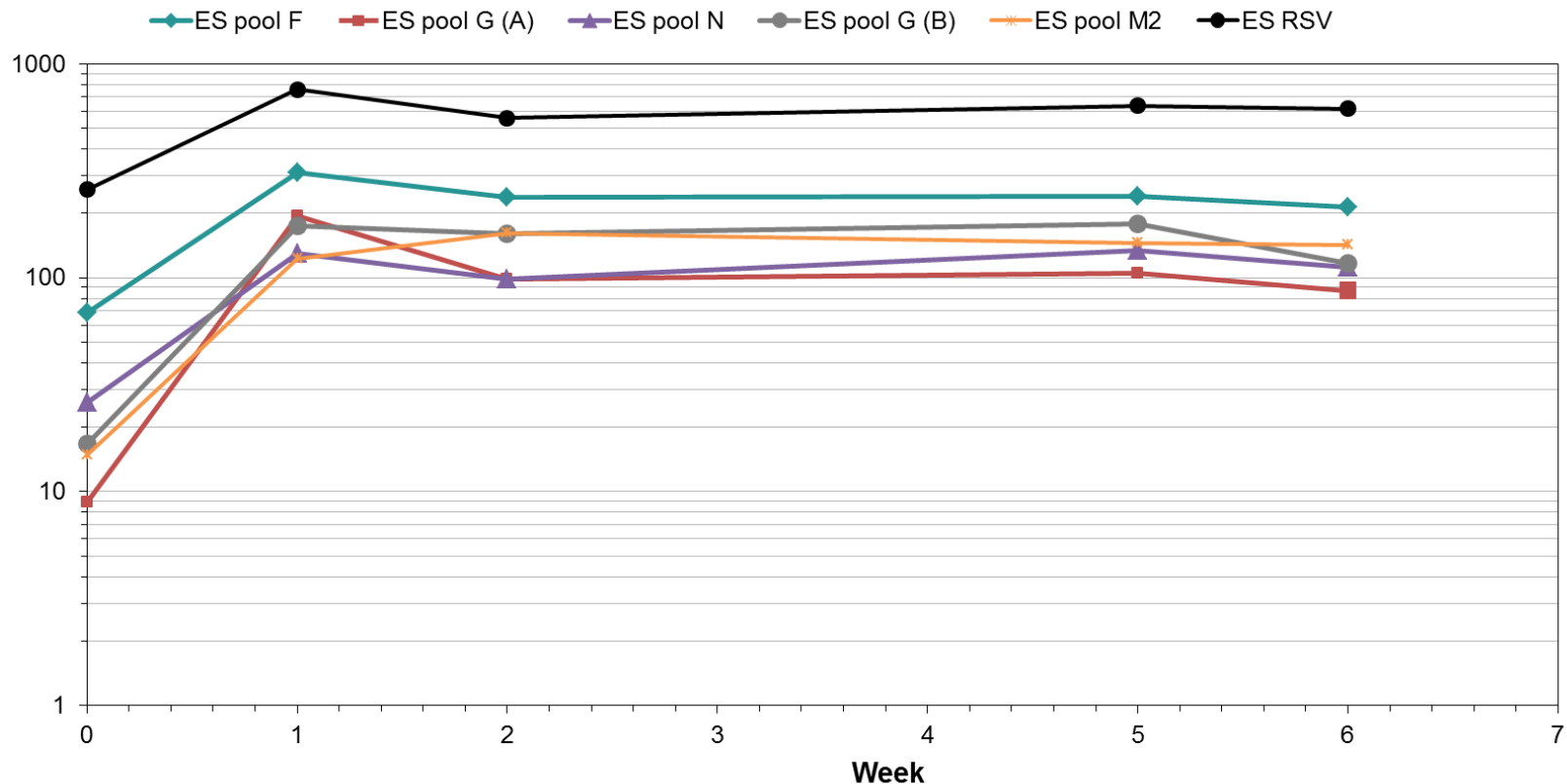
## MVA-BN RSV - a highly differentiated approach

- 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



# MVA-BN RSV - ADDITIONAL T-CELL DATA

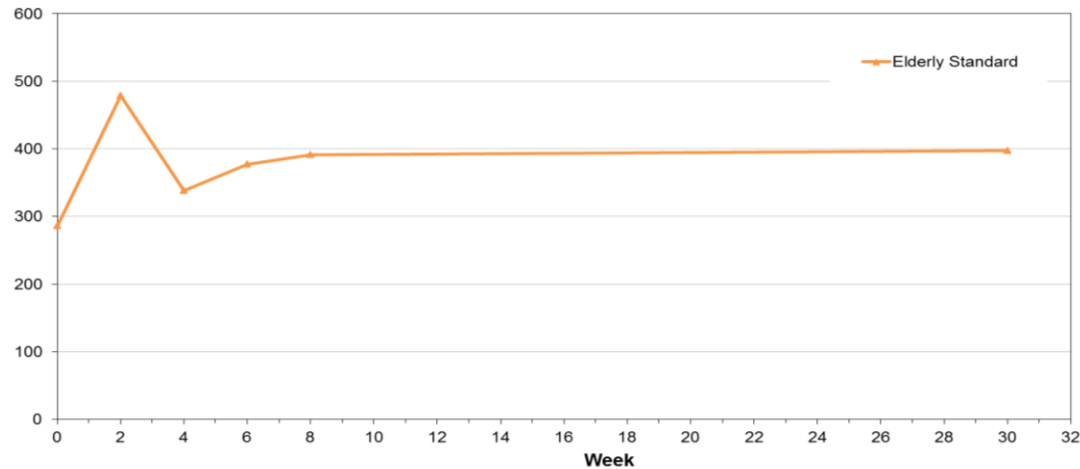
## RSV-specific T cell response (ELISPOT)



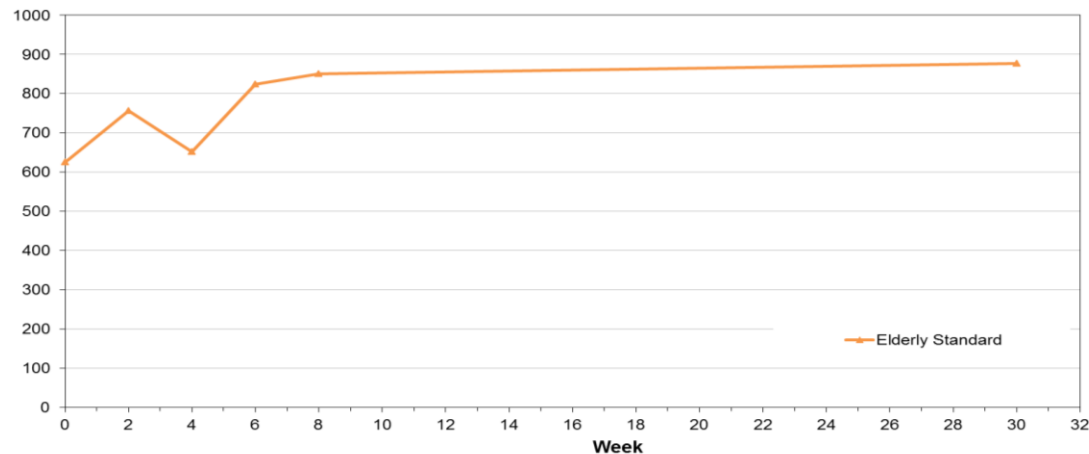
ES = Elderly Standard Dose group; vaccinations given at week 0 and week 4

# MVA-BN RSV - PHASE 1 FOLLOW-UP DATA

## RSV antibody response by IgA ELISA (GMT)



## RSV antibody responses by PRNT (A strain)



vaccinations given at week 0 and week 4

## MVA-BN RSV PHASE 2



Randomized, blinded, placebo-controlled dose ranging study

- 400 healthy subjects ( $\geq 55$  years old)
- Study will help identify optimal dose and schedule

Groups	N	Vaccine Dose	Schedule (Day)		Route
			0	28	
1	80	Low	MVA-BN RSV	Placebo	IM
2	80	Low	MVA-BN RSV	MVA-BN RSV	IM
3	80	High	MVA-BN RSV	Placebo	IM
4	80	High	MVA-BN RSV	MVA-BN RSV	IM
5	80	-	Placebo	Placebo	IM
Total	400				



# CV301 CANCER IMMUNOTHERAPY

## EXPLORING SYNERGIES IN COMBINATION WITH OTHER IMMUNE-MODULATING AGENTS

### Lung cancer

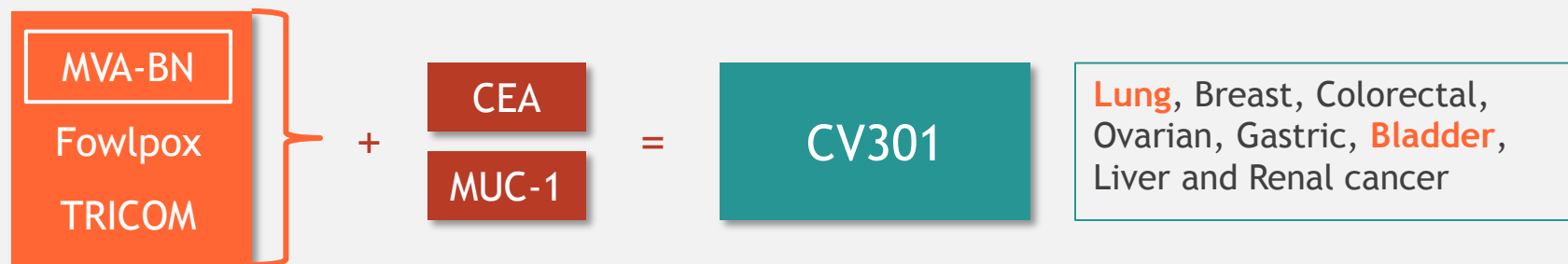
- Proof-of-concept study of CV301 plus nivolumab initiated
  - Second-line treatment, potential for first-line treatment
  - Bristol-Myers Squibb to supply nivolumab at no cost

### Bladder cancer

- Agreement with Roche to supply atezolizumab for planned study in bladder cancer

BN retains all commercial rights

NCSLC	BN sponsored
Bladder	BN sponsored
Other indications	Exploring combinations in company collaborations or with NCI



# PROOF-OF-CONCEPT STUDY OF CV301 & NIVOLUMAB 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



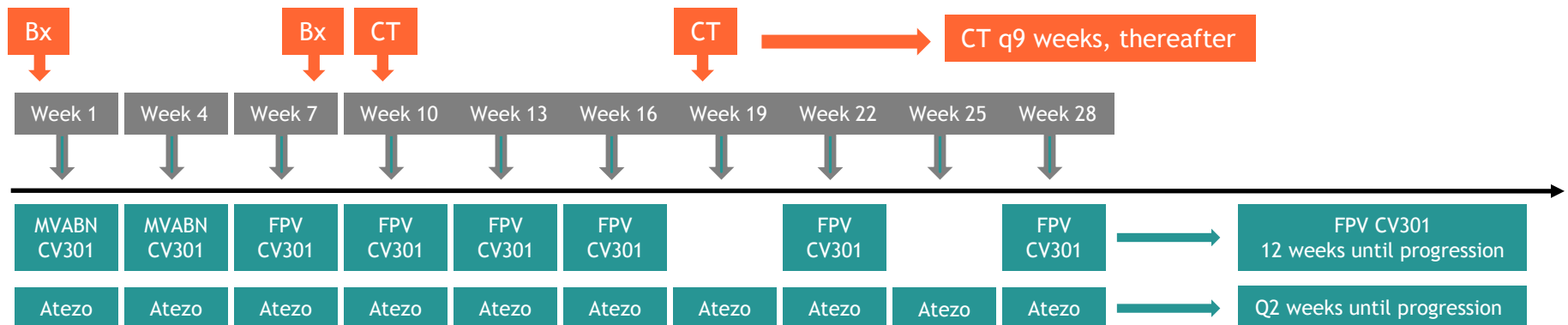
CV301 + nivo (n=60) nivo (mono) (n=60)

## Endpoints

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

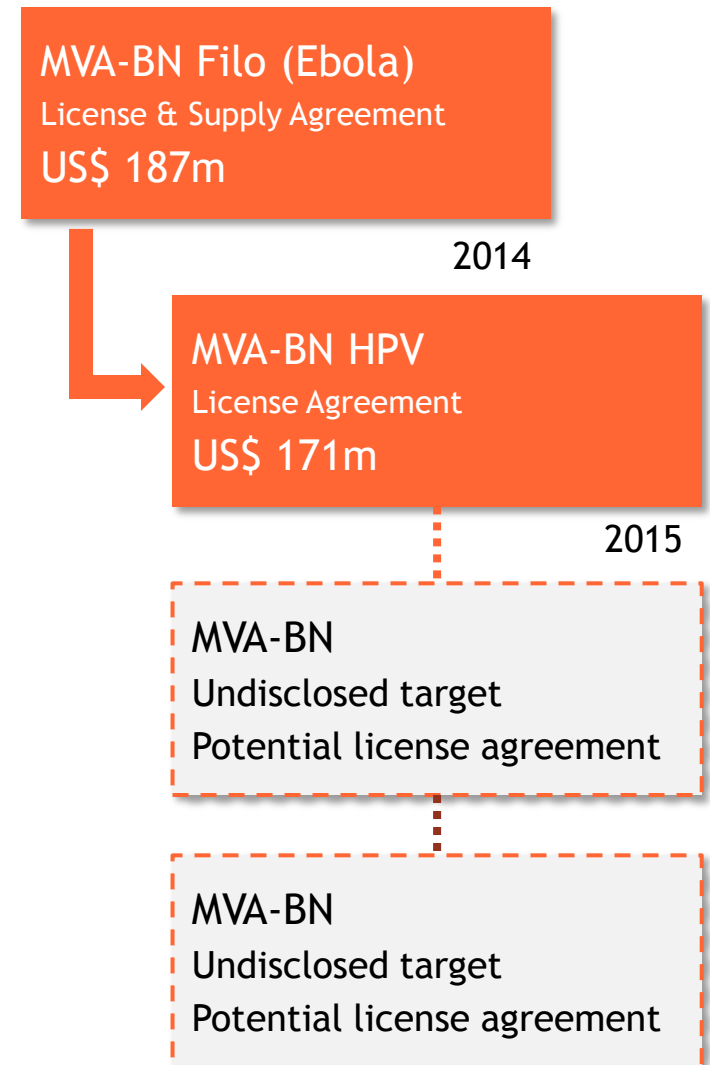
# CV301 + ATEZOLIZUMAB (ANTI PD-L1) IN 2ND LINE METASTATIC BLADDER CANCER

- Single-arm, combination of standard therapy (atezolizumab) + CV301
- Primary Endpoint: Improve OS compared with historical control (7.9 months)
- Secondary Endpoints = Early indicators possible:
  - objective response rate (control = 19%),
  - progression free survival (control median = 2.1 months)
- Exploratory = biomarker discovery
  - Inform future trial design and other indications



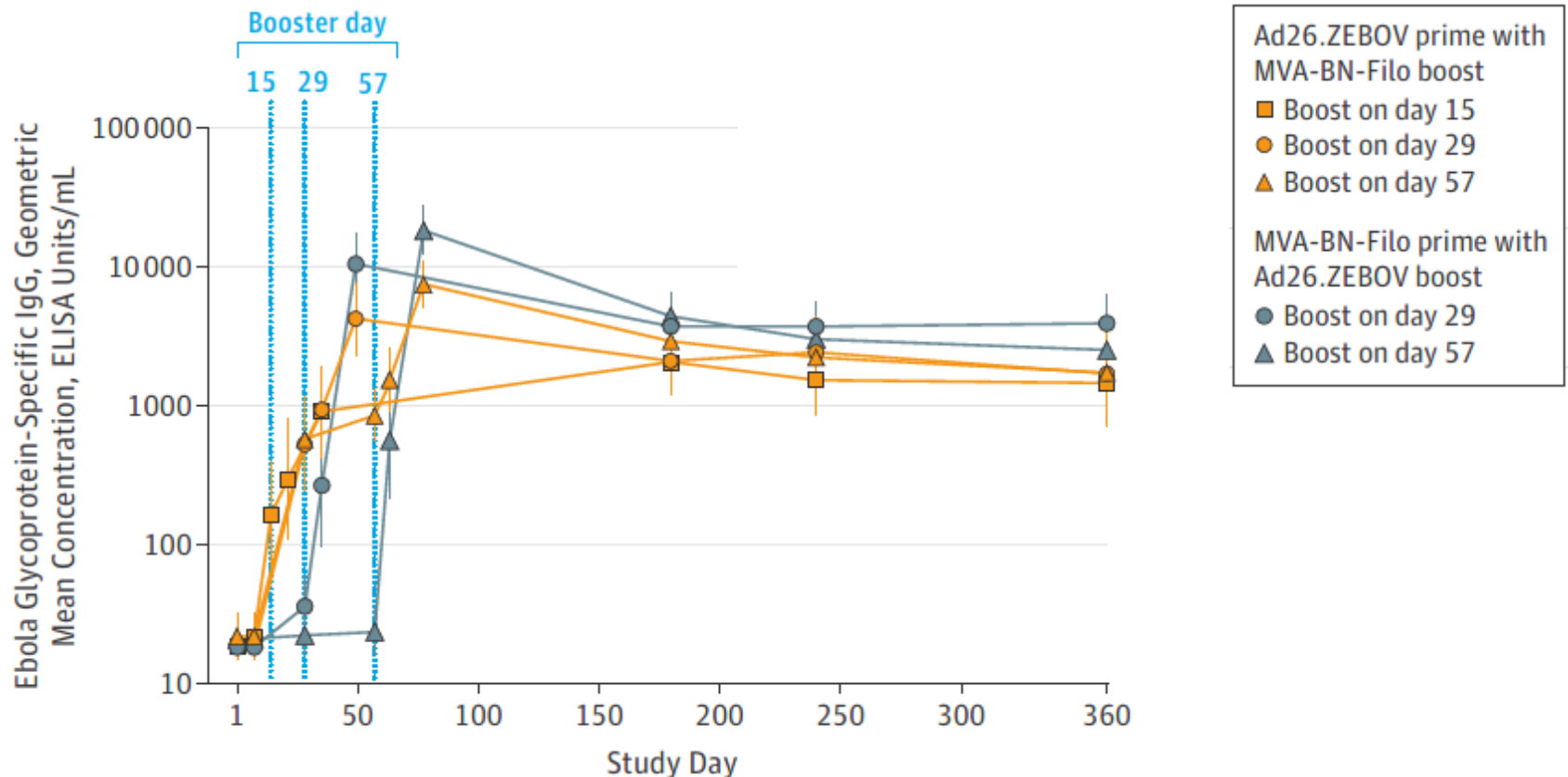
# OUR COLLABORATION WITH JANSSEN

- Janssen completed a submission for Emergency Use Assessment and Listing for the Ebola vaccine to the WHO
  - Phase 3 studies ongoing
  - Initiated Phase 1 study of a multivalent vaccine (Ebola, Sudan and Marburg viruses)
- HPV vaccine to start clinical trials in 2017
- Janssen retains option to license two additional disease targets



# EBOLA PHASE 1 DATA, 1-YEAR FOLLOW-UP










- The longest duration follow-up for any heterologous primary and booster Ebola vaccine schedule



JAMA, March 14, 2017: Immune Responses to Novel Adenovirus Type 26 and Modified Vaccinia Ankara-Vectors Ebola Vaccines at 1 Year

# PIPELINE



PRODUCT	INDICATION	ONGOING STUDIES	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	MARKET	COMMERCIAL RIGHTS
INFECTIOUS DISEASES								
IMVAMUNE liquid-frozen <sup>1)</sup>	<i>Smallpox</i>	1						 BAVARIAN NORDIC
IMVAMUNE freeze-dried	<i>Smallpox</i>	-						 BAVARIAN NORDIC
MVA-BN Filo	<i>Ebola/Marburg</i>	10						 janssen <small>PHARMACEUTICAL COMPANY a Johnson &amp; Johnson company</small>
MVA-BN RSV	<i>RSV</i>	1						 BAVARIAN NORDIC
MVA-BN HPV	<i>Chronic HPV Infection</i>	-						 janssen <small>PHARMACEUTICAL COMPANY a Johnson &amp; Johnson company</small>
CANCER IMMUNOTHERAPY								
PROSTVAC mono	<i>Prostate Cancer</i>	1						 Bristol-Myers Squibb
PROSTVAC mono/combo	<i>Prostate Cancer</i>	9						 Bristol-Myers Squibb
CV301 + nivolumab	<i>Lung Cancer (NSCLC)</i>	1						 BAVARIAN NORDIC
MVA-BN Brachyury	<i>Metastatic Tumors</i>	-						 BAVARIAN NORDIC

<sup>1)</sup> 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.



# ANTICIPATED SELECTED MILESTONES

## IMVAMUNE

- U.S. RFP for freeze-dried IMVAMUNE
- Top-line data for Phase 3 non-inferiority study
- Approval and Priority Review Voucher

## RSV

- MVA-BN RSV Phase 2 dosing study read out
- MVA-BN RSV additional study initiations

## JANSSEN

- Initiate HPV Phase 1 study in cervical cancer
- Potential expanded collaboration with Janssen on two additional infectious disease targets
- Data from Ebola prime-boost vaccine regimen
- Ebola vaccine pending approval for emergency use by WHO

## PROSTVAC

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

## CV301

- Initiate Phase 2 study of CV301 + atezolizumab in bladder cancer
- CV301 + checkpoint inhibitor proof-of-concept studies in additional indications

## BRACHYURY

- MVA-BN Brachyury Phase 2 initiation

# Q&A

**SAVE THE DATE**  
**SEPTEMBER 21, 2017**



**BAVARIAN NORDIC CAPITAL MARKETS DAY**  
**LE PARKER MERIDIEN HOTEL**  
**NEW YORK CITY**



