



ANNUAL REPORT **2015**



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.

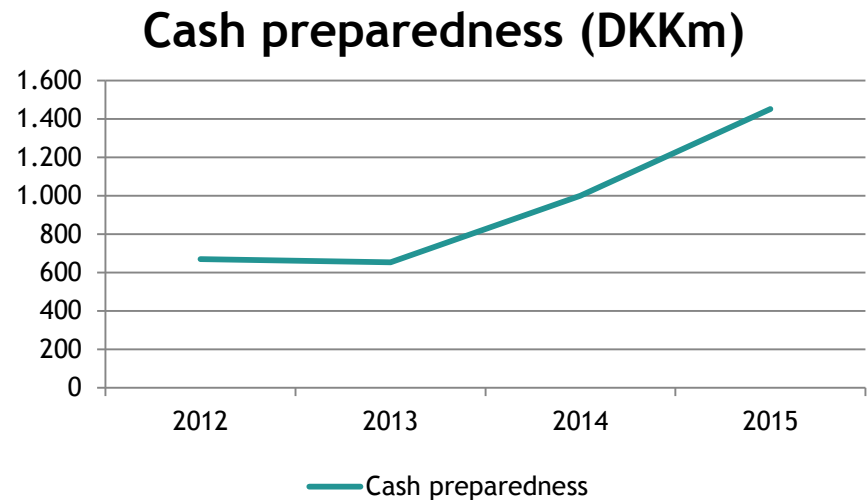
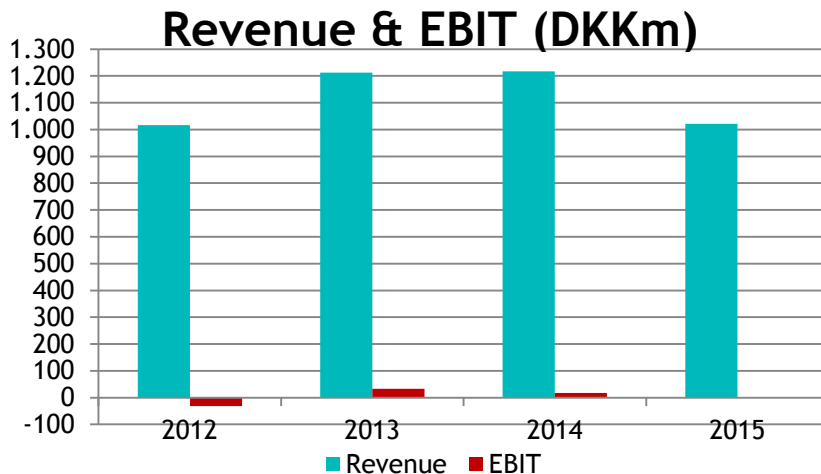


FINANCIALS

OLE LARSEN, CFO

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



2015 RESULTS IN LINE WITH EXPECTATIONS

- Revenues of more than DKK 1bn
 - 762 mDKK; deliveries of MVA-BN Filo to Janssen (112 mUSD)
 - 181 mDKK; ongoing R&D contracts (27 mUSD)
 - 78 mDKK; sale of IMVAMUNE to USA and rest of world (11 mUSD)
- Break-even result

		mDKK		mUSD	
2015		guidance	actual	guidance	actual
✓	Revenue	1,000	1,021	146	149
✓	EBIT	0	2	0	0
✓	Cash preparedness at year-end	1,450	1,451	212	212

USD/DKK = 6.83

FINANCIAL STATEMENTS

	mDKK		mUSD	
	FY 2015	FY 2014	FY 2015	FY 2014
Revenue	1,021	1,217	149	178
Production costs	415	495	61	72
Gross profit	605	722	89	106
Research and development costs	387	479	57	70
Distribution and administrative costs	217	226	32	33
Total operating costs	604	705	88	103
Income before interest and taxes (EBIT)	2	17	0	2
Financial income/loss	76	48	11	7
Income before company tax	78	64	11	9
Tax	18	38	3	6
Net profit for the period	59	26	9	4
Cash preparedness (end of period)	1,451	1,000	212	146

USD/DKK = 6.83

GROSS MARGINS

- Continued efficacy improvements in manufacturing
- “Learning costs” moving from single to multi product manufacturing
- New product mix
- The last 0.3 million IMVAMUNE doses delivered out of the 8 million dose contract

MVA-BN Filo

78%

IMVAMUNE

71%

(2014: 60%)

R&D
contracts

42%

(2014:
52%)

Overall

59%

(2014: 59%)

FINANCIAL OUTLOOK

2016 guidance - another year with break-even expected


- More than 90% of revenues will be recognized in 2H 2016
 - 750 mDKK from IMVAMUNE sales (110 mUSD)
 - 250 mDKK from R&D contracts (37 mUSD)
- Total R&D costs of 580 mDKK (85 mUSD) of which 475 mDKK (70 mUSD) will be recognized in the P&L
- Ongoing evaluation of financing options based on market conditions, including previously announced prospective registered public offering in the U.S. of the ADSs, the timing and terms of which have not yet been determined; year-end cash preparedness does not include proceeds from any prospective share issuance

2016E	mDKK	mUSD
Revenue	1,000	146
EBIT	0	0
Cash preparedness at year-end	1,300	190

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

All numbers are approximate

USD/DKK = 6.83



2015/2016 HIGHLIGHTS 2016 OUTLOOK

PAUL CHAPLIN, CEO AND PRESIDENT

2015/2016 HIGHLIGHTS

PARTNERSHIPS

- Global commercialization agreement for PROSTVAC with Bristol-Myers Squibb - potential value of \$975M including option and milestone payments and \$60M upfront.
- Product license agreement with Janssen (Johnson & Johnson) for MVA-BN HPV - \$9M upfront, & potential of 162M in development & sales milestones

CONTRACTS

\$181M vaccine supply and R&D contracts from the US government

- \$15M expansion of NIH contract for Filovirus vaccine development (June 2015)
- \$133M INVAMUNE bulk order received by BARDA (July 2015)
- \$33M R&D MVA-BN Filo BARDA contract (subcontractor to Janssen award)

PIPELINE DEVELOPMENT

Multiple clinical studies initiated

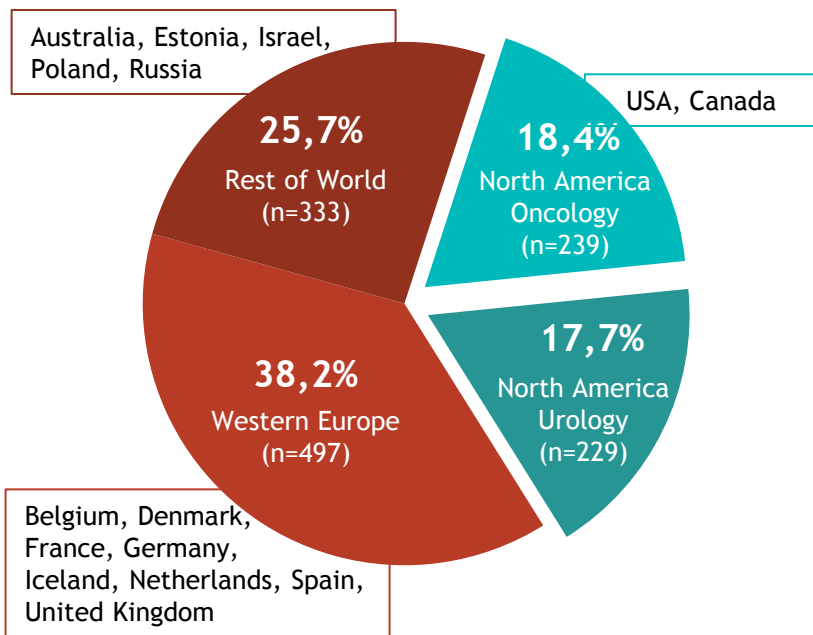
- MVA-BN RSV Phase 1 in U.S.
- PROSTVAC Phase 2 active surveillance study in men with localized prostate cancer
- PROSTVAC + docetaxel combination Phase 2 study in metastatic prostate cancer (2016)
- PROSTVAC Phase 2 study in non-metastatic castration sensitive prostate cancer (2016)
- PROSTVAC first interim analysis has occurred; study continues as planned (2016)
- Ebola prime boost phase 3 study
- Reported pivotal Phase 2 & 3 IMVAMUNE data
- Reported long-term survival Phase 1 data of combination of PROSTVAC and ipilimumab
- Reported Phase 1 Brachyury data in 38 patients with advanced cancer
- Reported Phase 1 Ebola data

PROSTVAC PHASE 3 STUDY

PROSPECT

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

Randomization by region (N=1,297)



3 study arms

PROSTVAC + GM-CSF

PROSTVAC

Placebo

Injections

- Average was **6.1 injections¹**
- Randomized Phase 2 trial (n=122) had average of 5.4 injections²
- An increased number of injections is expected to improve the clinical outcome for patients receiving the active drug.

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: INTERIM ANALYSES UNDERWAY

First interim analysis of the PROSPECT Phase 3 study has occurred

- A recent review by the Data Monitoring Committee informed BN to “Continue the trial without modification”
- Interim 1 was an analysis of each of the active PROSTVAC arms (with or without GM-CSF) versus placebo, thus requiring at least 214 events per comparison (equals 40% of the 534 events required for final overall survival analysis)
- 2 additional interim analyses remain
- Final overall survival data anticipated in 2017

Interim Analysis #1	✓	214 events	40%
Interim Analysis #2		321 events	60%
Interim Analysis #3		427 events	80%
Final Overall Survival Analysis		534 events	100%

PROSTVAC COMBINATION TRIALS

TWO NEW TRIALS PLANNED FOR INITIATION

Further investigation of PROSTVAC in collaboration with BMS

- Two new investigator-sponsored trials planned for initiation

Phase 2 (n=75)

Open label combination trial in localized prostate cancer using PROSTVAC and ipilimumab as neoadjuvant therapy.

Randomization 1:1:1

PROSTVAC

ipilimumab

PROSTVAC + ipi

Sponsor: UCSF
Clinicaltrials.gov
NCT02506114

Phase 2 (n=28)

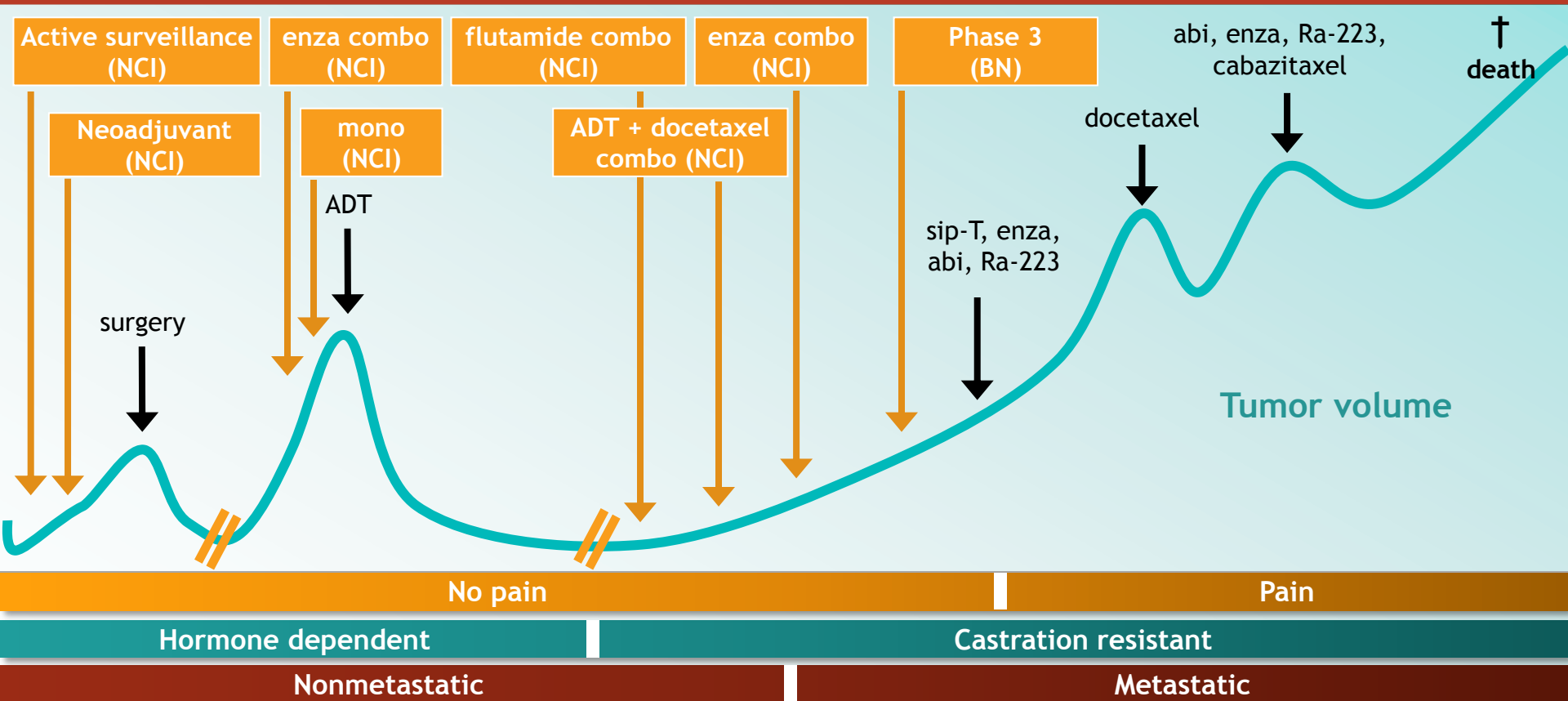
Open label combination trial in prostate cancer using PROSTVAC, ipilimumab and nivolumab as neoadjuvant therapy

PROSTVAC + ipi + nivo

PROSTVAC + ipi

Sponsor: NCI

STUDIES SPAN PROSTATE CANCER DISEASE LANDSCAPE



- **Mechanism of action (MOA)**
 - Immune infiltration to tumor, immune response, biomarkers, and PSA kinetics
- **Use in combination**
 - With currently approved therapies for mCRPC, and with checkpoint inhibitors
- **Use in earlier prostate cancer to support future label expansion**
 - More studies planned in early disease indications

CV-301 FOR MULTIPLE CANCERS

CV-301 development strategy

- Combination treatment with checkpoint inhibitor(s)
- Short-term clinical outcomes possible (Overall Response Rate, Progression-Free Survival)
- Partnering opportunity based on proof-of-concept data
- Additional planned and ongoing NCI-sponsored studies

New and improved vaccine construct based on MVA-BN



CV-301 PRODUCT DEVELOPMENT STRATEGY

Leverage Existing Clinical Data

Preliminary evidence of efficacy generated in multiple clinical studies.

Safety data with over 300 subjects treated.

CV-301 in Combination with Immune Checkpoint Inhibitors

NCSLC

BN sponsored

Bladder

Exploring combinations with PD-1/PD-L1 in company collaborations or with NCI

Colorectal

EXPANSION OF JANSSEN COLLABORATION: HPV VACCINE

\$171M AGREEMENT SIGNED IN DECEMBER 2015

- Subsequent to the Ebola collaboration, BN and Janssen agreed to collaborate on three additional infectious disease targets
- The first indication now licensed with Janssen
- A therapeutic vaccine for individuals with an active human papillomavirus (HPV) infection
 - Novel approach for early treatment and interception of HPV-induced cancers
 - High-risk HPV types cause approximately 5 percent of all cancers worldwide



MVA-BN HPV deal structure

- Total potential agreement value \$171 million including \$9 million upfront plus milestone payments and single-digit royalties on sales
- Janssen expected to initially focus on infected women at risk for cervical cancer, and then head and neck cancers
- Bavarian Nordic to retain manufacturing of MVA based component

COMMERCIAL VACCINES: RSV

LARGE UNMET MEDICAL NEED: CHILDREN & ELDERLY

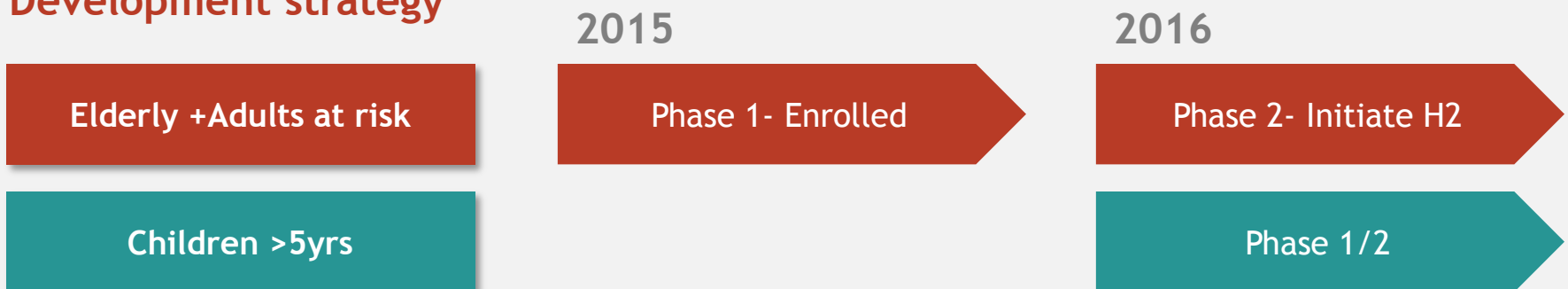
RSV: Respiratory Syncytial Virus

- No approved vaccine; high unmet medical need
- Responsible for a similar number of deaths as the flu in children up to 14, as well as in the elderly population
- Results in a high number of hospitalizations

MVA-BN RSV vaccine candidate

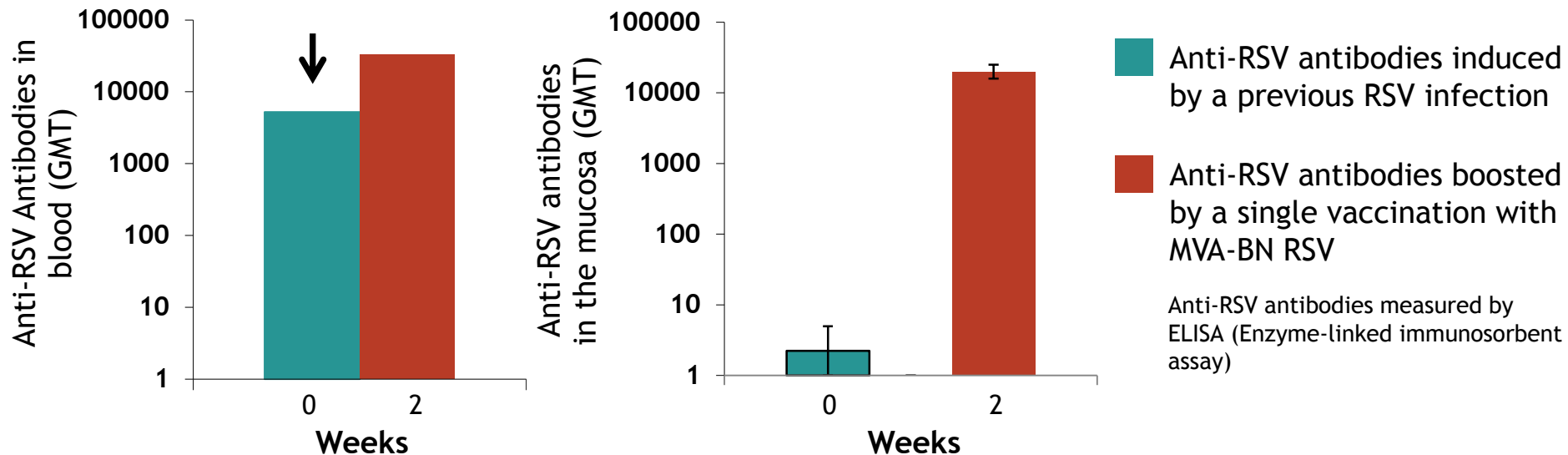
- Demonstrated strong immune response
- Blood and mucosal protection (*key differentiator*)
- Protection against both RSV subtypes (A&B) in preclinical models

Development strategy



MVA-BN RSV BOOSTS PRE-EXISTING RESPONSES

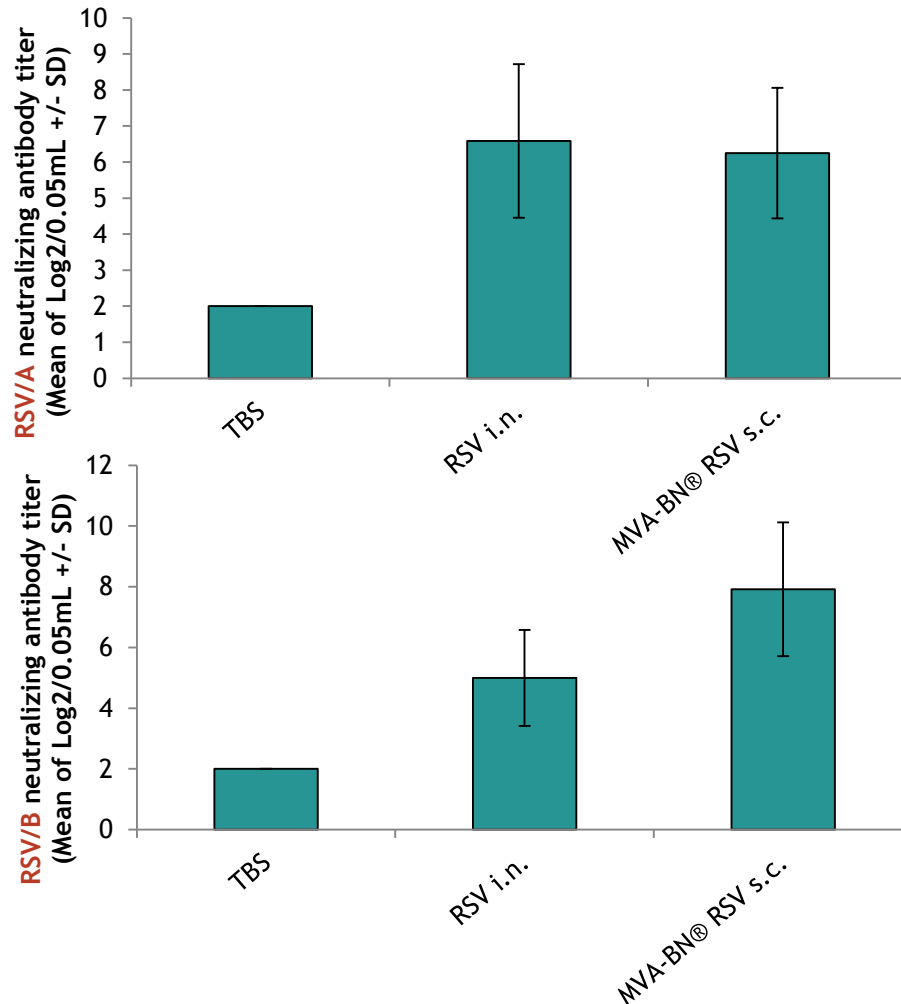
Preclinical data



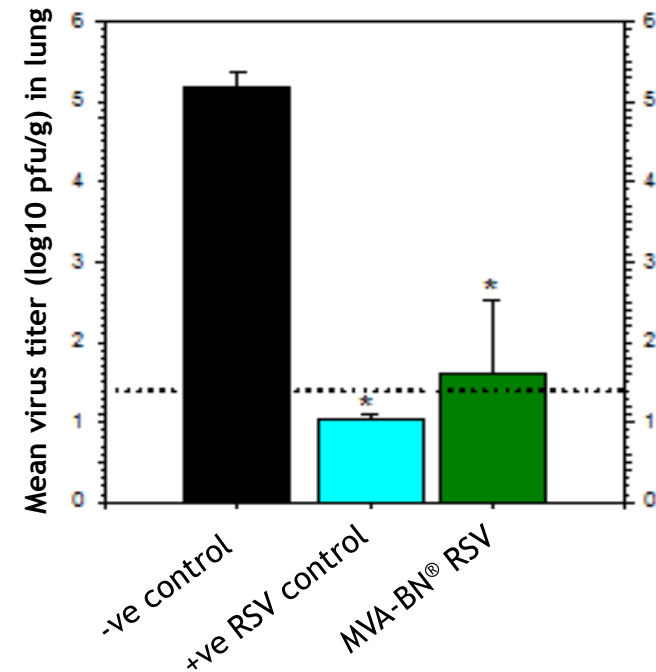
- Animals that had previously been infected (and survived) an RSV infection were vaccinated at week 0.
- Model mimics the situation of adults that have all been exposed to RSV
- Antibodies against RSV were boosted >7-fold & >75-fold in the blood and mucosa (lung) following a single vaccination with MVA-BN RSV

MVA-BN RSV IS IMMUNOGENIC & EFFICACIOUS IN COTTON RATS

Neutralizing Antibodies @ A & B Strain



RSV Clearance from the lung



- 2nd study confirmed the promising results that MVA-BN RSV was equally immunogenic and efficacious as a natural RSV infection (+ve control).
- A 3rd study is being planned to investigate MVA-BN RSV given i.n. in cotton rats

















MVA-BN RSV PHASE 1 INITIATED IN THE UNITED STATES

- Fully enrolled Phase 1, randomized, single-blind, monocenter, placebo controlled
- Healthy subjects, 18 - 65 years of age, N = 63
- **Primary objective:** Safety and reactogenicity of MVA-mBN294B (MVA-BN RSV vaccine)
- **Secondary objective:** RSV-specific (ELISA, PRNT, ELISPOT/ICS) and vaccinia-specific immune response to MVA-BN-RSV vaccine

Groups	N	Age (years)	Vaccine	Dose per 0.5 ml (nominal titers)	Schedule (Days)
1	18+3	18-49	MVA-BN RSV /placebo	1×10^7 TCID ₅₀	0-28
2	18+3	18-49	MVA-BN RSV /placebo	1×10^8 TCID ₅₀	0-28
3	18+3	50-65	MVA-BN RSV /placebo	1×10^8 TCID ₅₀	0-28
Total	54+9 = 63				

Data expected 1H16

CLINICAL PIPELINE

PRODUCT	CANDIDATE INDICATION	COMMERCIAL RIGHTS	PRIMER / BOOSTER	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	APPROVED	STATUS / EXPECTED MILESTONES
Infectious Disease									
IMVAMUNE / IMVANEX (LIQUID FROZEN)	Smallpox		MVA-BN MVA-BN	Approved in Canada and the European Union					• Approved in Canada and the European Union
	Smallpox		MVA-BN MVA-BN	Phase 3 in US (non-inferiority)					• Complete enrollment in 2017
IMVAMUNE (FREEZE DRIED)	Smallpox		MVA-BN MVA-BN	Phase 2 complete					• Manufacturing validation
MVA-BN Filo	Ebola / Marburg		AdVac ^(a) MVA-BN						• Data from multiple trials in 2016
MVA-BN RSV	RSV		MVA-BN MVA-BN	Fully enrolled					• Phase 1 trial data in 1H16
HPV Vaccine	HPV		AdVac ^(a) MVA-BN						• Deal signed in December 2015
Cancer Immunotherapy									
PROSTVAC	mCRPC		Vaccinia Fowlpox	PROSPECT fully enrolled					• Three interim analyses likely starting in 1Q16 with top-line data in 2017
	Localized Prostate Cancer		Vaccinia Fowlpox						• NCI enrolling Phase 2 trial
	Localized Prostate Cancer (neoadjuvant)		Vaccinia Fowlpox						• NCI Phase 2 trial data in 2016
	Non-Metastatic Castration Sensitive Prostate Cancer		Vaccinia Fowlpox						• NCI enrolling Phase 2 trial
	mCRPC		Vaccinia Fowlpox	+ XTANDI (enzalutamide)					• NCI enrolling Phase 2 trial
	Metastatic Castration Sensitive Prostate Cancer		Vaccinia Fowlpox	+ ADT and docetaxel					• NCI enrolling Phase 2 trial
	Non-Metastatic Prostate Cancer		Vaccinia Fowlpox	+ XTANDI (enzalutamide)					• NCI Phase 2 trial data in 1H16
	Prostate Cancer		Vaccinia Fowlpox	ipilimumab					• NCI Phase 1 trial enrollment complete
CV 301	Bladder Cancer		Vaccinia Fowlpox ^(c)						• NCI enrolling Phase 2 NCI trial
MVA-BN Brachyury	Solid Tumors		MVA-BN MVA-BN ^(d)						• Phase 1 data reported in 4Q15

(a) An adenovirus primer from Janssen.

(b) BMS would have complete commercial rights to PROSTVAC, regardless of treatment setting, should they exercise their licensing agreement.

(c) Anticipated transition to MVA primer.

(d) Anticipated transition to Fowlpox booster.

ANTICIPATED SELECTED MILESTONES

2016/2017

PROSTVAC

prostate cancer

- Interim analyses of Phase 3 study
- Phase 3 top-line data
- Initiate Phase 2 study in combination with ipilimumab in collaboration with BMS
- Initiate NCI-sponsored Phase 2 study in combination with ipilimumab and nivolumab
- Data from NCI-sponsored Phase 2 trials
- New NCI-sponsored combination trials

IMVAMUNE

smallpox vaccine

- Finalize manufacturing activities to support a U.S. EUA for freeze-dried IMVAMUNE
- Initiate manufacturing and storage of IMVAMUNE bulk for the U.S. Government
- Additional Rest of World orders
- Complete enrollment of Phase 3 non-inferiority study

Pipeline

projects

- MVA-BN RSV Phase 1 data
- MVA-BN RSV Phase 2 initiation
- MVA-BN Brachyury Phase 2 initiation
- CV-301 + checkpoint inhibitor Phase 2 initiation in lung cancer
- CV-301 + checkpoint inhibitor Phase 2 initiation in additional indications
- Initiate NIH-sponsored Phase 1 trial of multivalent MVA-BN Filo
- Complete Phase 2 and Phase 3 studies of the Ebola prime-boost vaccine regimen
- Potential expanded collaboration with Janssen on additional infectious disease targets

Q&A

