

# **Q2** **2017**

*INTERIM RESULTS AS OF JUNE 30, 2017*



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.*

# HIGHLIGHTS

## FOR THE SECOND QUARTER 2017 AND UP TO DATE



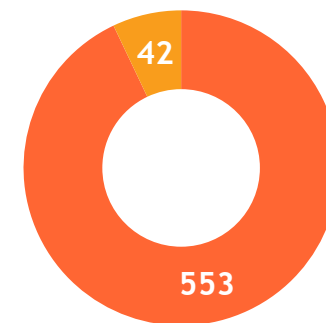
- J&J \$879M deal for HIV and Hepatitis B
  - Equity investment of \$33M, bringing total ownership in BN to 5.77%
- Positive RSV Ph 2 data
  - Identification of single shot solution for future development
- IMVAMUNE US RFP process update
  - Freeze-dried contract negotiation underway
- PROSPECT timing update
  - Interim analysis #3 scheduled for September
  - Full data by year end 2017
- Hiring of Dr. Tommi Kainu, EVP Chief Business Officer

# FINANCIAL SUMMARY AND OUTLOOK

## H1 financials as expected

- Revenues in H1 2017 were largely derived from the sale of IMVAMUNE bulk drug substance (BDS) to USG
- Remaining ~250 mDKK for IMVAMUNE BDS expected in Q3
- PROSTVAC upfront of ~400 mDKK to be recognized as revenue in Q4 upon reporting of PROSPECT results
- FY revenue and EBIT expectations maintained
- YE cash preparedness was raised after entering new license agreement with Janssen in July

## Revenue H1 2017



- IMVAMUNE US + RoW
- R&D Contracts

	mDKK			mUSD		
	6m 2017	6m 2016	FY2017E	6m 2017	6m 2016	FY2017E
Revenue	595	139	1,300	91	21	199
EBIT	99	(207)	350	15	(32)	54
Cash preparedness, period-end	2,704	1,894	2,600	415	290	399

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

USD/DKK = 6.52 (as of June 30, 2017)

All numbers are approximate.

# FINANCIAL STATEMENTS



mDKK	6m 2017	6m 2016	FY 2016
Revenue	595	139	1,007
Production costs	177	47	298
<b>Gross profit</b>	<b>418</b>	<b>92</b>	<b>709</b>
Research and development costs	212	193	463
Distribution and administrative costs	107	105	213
<b>Total operating costs</b>	<b>319</b>	<b>299</b>	<b>676</b>
<b>Income before interest and taxes (EBIT)</b>	<b>99</b>	<b>(207)</b>	<b>33</b>
Financial income/loss	(47)	2	7
<b>Income before company tax</b>	<b>52</b>	<b>(204)</b>	<b>40</b>
Tax	12	(50)	9
<b>Net profit for the period</b>	<b>40</b>	<b>(155)</b>	<b>31</b>
<b>Cash preparedness (end of period)</b>	<b>2,704</b>	<b>1,894</b>	<b>2,292</b>

USD / DKK = 6.52

# BAVARIAN NORDIC'S GOAL

To develop innovative and safe therapies against cancer and infectious diseases; to improve the health and quality of life for children and adults.

## CANCER

**PROSTVAC** *improving survival*

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**HPV** *preventing cancer before it starts*

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**CV301 &  
Brachyury  
in combination  
therapies** *potentially  
curing cancer*

## INFECTIOUS DISEASES

**RSV** *protecting the broader  
population against diseases  
with no approved therapies*

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**Smallpox /  
Ebola** *preparation and  
protection against  
global pandemic threats*

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**HIV / HBV** *seeking a functional cure*

# OUR COLLABORATION WITH JANSSEN

- **HIV + Hepatitis B**

Recent license agreement with upfront payment, equity investment and potential milestones of \$879m, and royalties

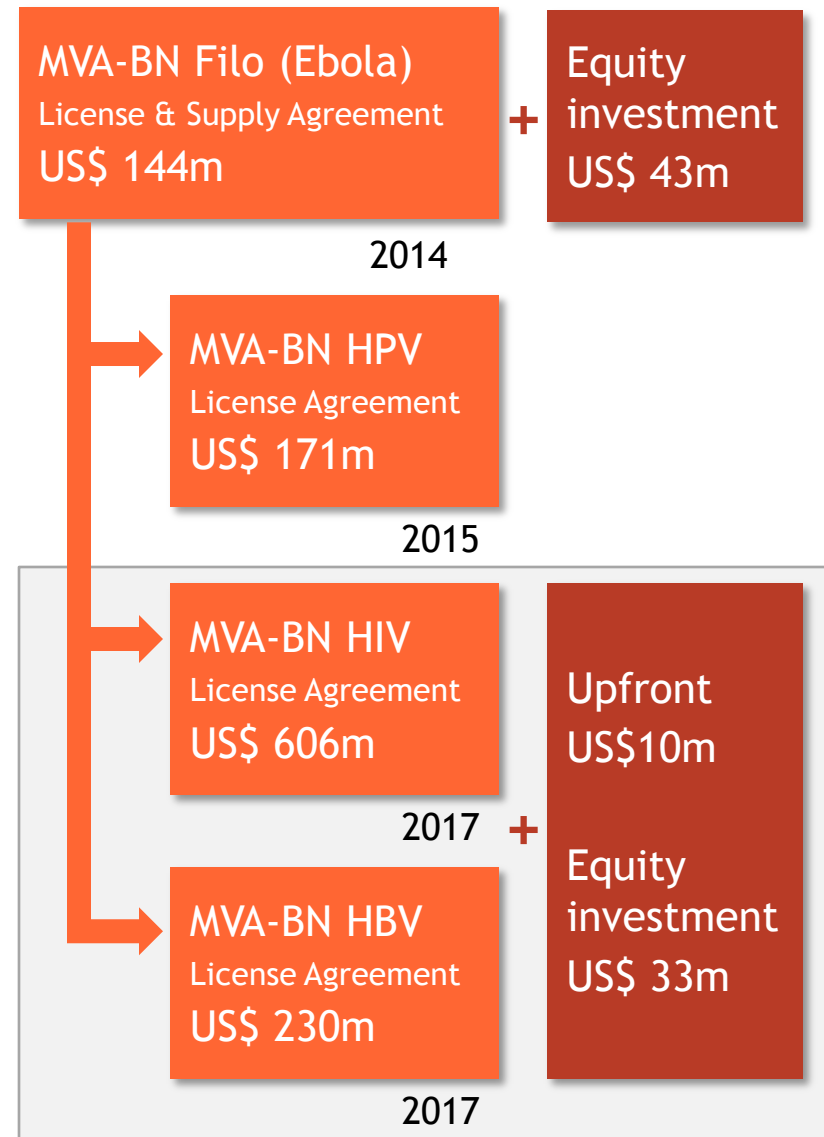
- **HPV**

Vaccine to start clinical trials in 2017

- **Ebola**

Janssen has completed a submission for Emergency Use Assessment and Listing to the WHO

Phase 1, 2 and 3 studies ongoing



# MOVING TOWARDS FINAL DATA FOR PROSTVAC

## ADDITIONAL COMBINATION STUDIES CONTINUES TO EXPAND POTENTIAL

- 8 completed and 11 ongoing trials
- 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%	Sep 2017
Final Analysis	534 events	100%	Q4 2017

*Estimated timing of events*

**Minimum duration of follow up in PROSPECT STUDY now >32 months**

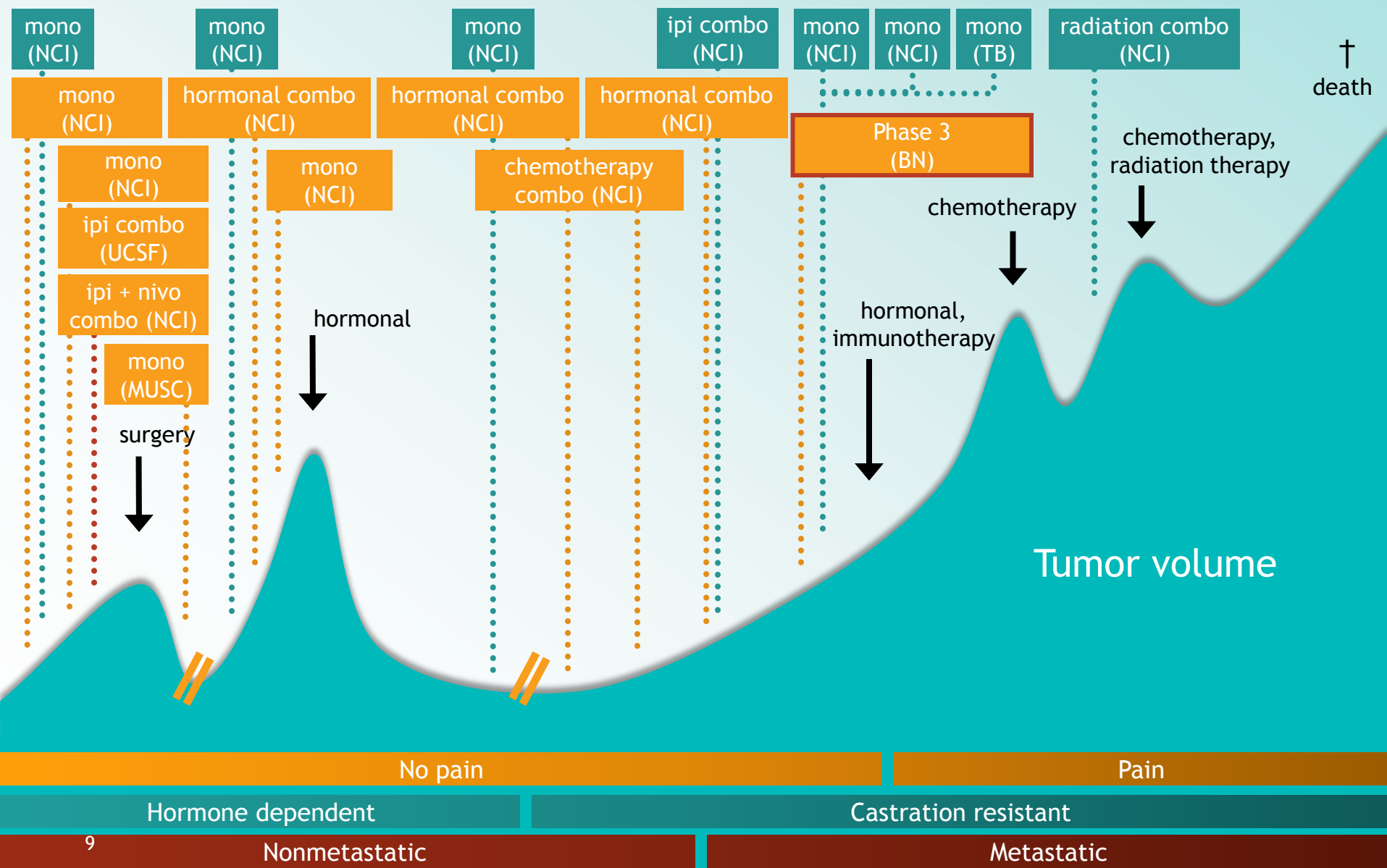


# PROSTVAC STUDIES

## SPAN PROSTATE CANCER DISEASE LANDSCAPE

COMPLETED

ONGOING



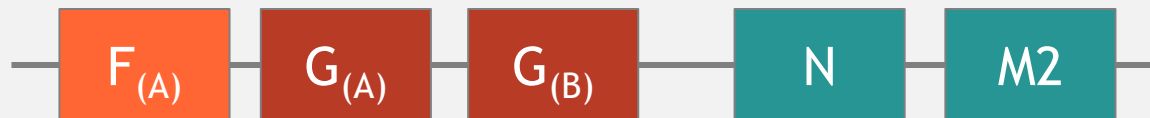
# BUILDING A UNIVERSAL RSV VACCINE

## WHY ARE WE DIFFERENT?

- Historical vaccine development provided incomplete protection
  - Possibly related to:
    - Lack of T cell production
    - Lack of mucosal protection
    - Poor duration of protection (i.e. not lasting a full season)
- Our platform allows for broad protection against multiple targets
- Boosting the natural immunity we all possess

### MVA-BN RSV - a highly differentiated approach

- By encoding 5 distinct targets of RSV, we have built our vaccine to equip the immune system with enough information to protect against a potential infection, regardless of serotype (A or B)



# RSV PHASE 2 DATA SUMMARY



- A 421 subject Phase 2 confirms the strong findings from Phase 1
  - Induction of a significant and **broad antibody** and **T cell response**
  - Induction of a **mucosal immune response** that may be important for protection against RSV
  - Both clinical studies have mirrored the preclinical immunological data where we also see a robust protection against both RSV subtypes (A&B)
- Phase 2 has established that a only a **single vaccination** is required
- 6 month follow-up data are ongoing
- Booster study will evaluate the immune responses 12 months post vaccination and an annual booster effect

# RSV NEXT STEPS

- **Phase 2 Booster Study:**

- Participants from both single shot dose levels will continue into the 2017/2018 RSV season
- Subjects will initially be evaluated to determine immunogenicity levels from prior season dosing (12 month durability)
- Subjects will then receive another booster shot of MVA-BN RSV and will be followed to help determine frequency of dosing
  - Dosing to commence Q3 2017
  - Top-line data Q2 2018
- In parallel, an End of Phase 2 Meeting is planned for 2018 to initiate discussions on potential registration studies

Groups	N	Vaccine Dose	Route
1	40	1x10 <sup>8</sup>	IM
2	40	5x10 <sup>8</sup>	IM
Total	80		



# CV301

Transitioning to first line therapy

Aligning combination treatments  
to reflect the commercial  
landscape

# CV301 - POTENTIAL IN MULTIPLE SOLID TUMORS

- Our platform is ideal for "immunogenic intensification"
- CV301 is engineered to create T-cells which target CEA and MUC1
- Goal of becoming preferred treatment in combination with any checkpoint inhibitor
  - Strong preclinical evidence of combination synergies
- Only approx. 1 in 5 patients respond to checkpoint inhibitors
  - How can we convert the non-responders?

Carcinoma	CEA	MUC1
Colorectal	>90%	>90%
Pancreatic	>95%	>95%
Lung <sup>1</sup>	70%	>80%
Breast	50%	>90%
Bladder	70%	>90%

# CV301 STRATEGY

## IMMUNOTHERAPY FOR MULTIPLE CANCERS



### Exploring synergies in combination with checkpoint inhibitors

#### Non-small cell lung cancer

BN sponsored

- Proof-of-concept study of CV301 plus KEYTRUDA (pembrolizumab)
- First-line maintenance therapy study planned

#### Bladder cancer

BN sponsored

- Collaboration with Roche to supply TECENTRIQ (atezolizumab) at no cost for planned Phase 2 study



#### Other indications

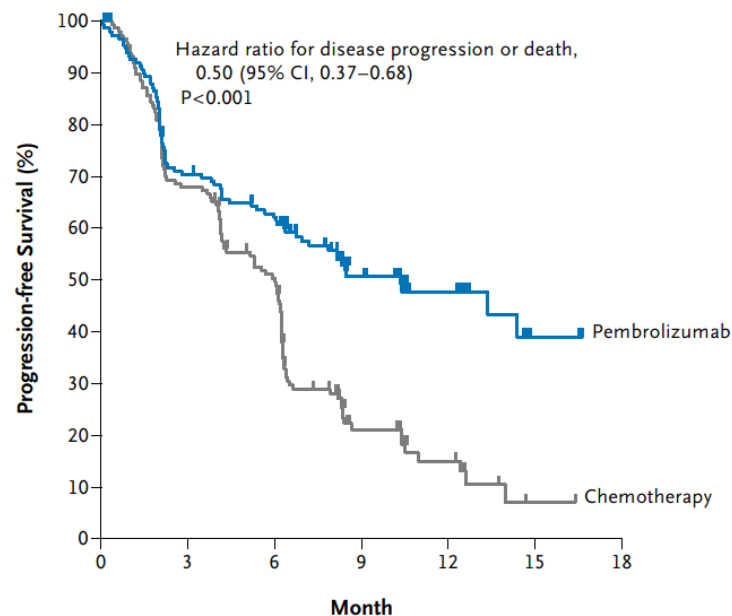
- Bavarian Nordic retains all commercial rights in lung, bladder, colorectal, breast, ovarian, gastric, liver and renal cancer

Exploring combinations in company collaborations or with NCI

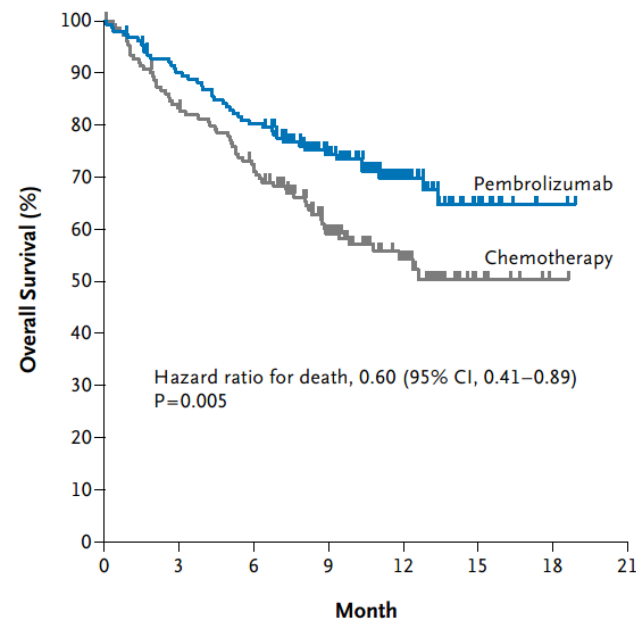
# SHIFTING SANDS IN TREATMENT LANDSCAPE

## Pembrolizumab (KEYTRUDA) versus Chemotherapy for PD-L1-Positive Non-Small-Cell Lung Cancer

Reck et.al., N Engl J Med 2016



No. at Risk							
Pembrolizumab	154	104	89	44	22	3	1
Chemotherapy	151	99	70	18	9	1	0



No. at Risk								
Pembrolizumab	154	136	121	82	39	11	2	0
Chemotherapy	151	123	106	64	34	7	1	0

ASCO update

ORR  
44.8% vs 27.8%

OS @12 mos  
70.3% vs 54.8%

OS @18 mos  
61%



# REVISED PROOF-OF-CONCEPT STUDY OF CV301 & KEYTRUDA IN FIRST LINE MAINTENANCE NSCLC

## Phase 1 - Completed

Safety CV301 single agent  
(n=12)

## Phase 1b - Ongoing

Single dose combinations of both CV301 with OPDIVO and CV301 with KEYTRUDA (n=6 pt each arm)

## Phase 2

Multi-center trial. Up to 20 sites in USA (n=176)

Cohort 1 (n=53): High PD-L1 expression  
Randomize 1:2

KEYTRUDA  
n=18

KEYTRUDA  
+ CV301  
n=35

Cohort 2 (n=123)

Randomize 1:2

KEYTRUDA  
± Pemetrexed  
n=41

KEYTRUDA  
+ CV301  
± Pemetrexed  
n=82

## Endpoints remain the same:

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

# IMVAMUNE FREEZE-DRIED RFP PROCESS UPDATE



- June: Notice of intent from HHS/BARDA re. sole source contract for freeze-dried smallpox vaccine
  - Initial award outlines \$100M investment
- RFP issued July
- BN response to RFP submitted (end of July)
- Award anticipated in fiscal 2017 (September 30th)



# ***CAPITAL MARKETS DAY***

## ***SEPTEMBER 21, 2017***

### ***NEW YORK CITY***



**SIGN UP:** *[bavarian-nordic.com/cmd](http://bavarian-nordic.com/cmd)*





# CAPITAL MARKETS DAY

## SELECTED FEATURED SPEAKERS



**James Gulley, M.D., Ph.D.**

Chief, Genitourinary Malignancies Branch, Senior Investigator, Head, Immunotherapy Section, Director, Medical Oncology Service, CCR Office of the Clinical Director, NCI

*Principal Investigator on PROSPECT study*



**Ravi A. Madan, M.D.**

Associate Research Physician, Genitourinary Malignancies Branch, Clinical Director, Genitourinary Malignancies Branch, NCI

*Principal Investigator on several PROSTVAC studies*



**Douglas McNeel M.D., Ph.D.**

Associate Professor in the Department of Medicine, division of Hematology/Oncology, at the University of Wisconsin-Madison

# ANTICIPATED SELECTED MILESTONES



## IMVAMUNE

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

## RSV

- Report 6 months follow-up data from Phase 2 study and continue booster-study of subjects that received a single shot
- Establish meeting with FDA to determine appropriate registration pathway for elderly adults that have a high morbidity from RSV

## JANSSEN

- Initiate HPV Phase 1 study in cervical cancer
- Data from Ebola prime-boost vaccine regimen

## PROSTVAC

- Phase 3 top-line data including third interim analysis
- Data from NCI-sponsored Phase 2 trials

## CV301

- Report Phase 1 data of combination of CV301 and OPDIVO
- Transition to first line NSCLC combination of CV301 and KEYTRUDA in Phase 2 study
- Initiate Phase 2 study with Roche in bladder cancer
- CV301 + checkpoint inhibitor proof-of-concept studies in additional indications

## BRACHYURY

- MVA-BN Brachyury Phase 2 initiation

# Q&A



