

Q1 2019

INTERIM RESULTS AS OF MARCH 31, 2019



1994 **25** 2019

YEARS

OF GREAT ACHIEVEMENTS
IN THE VACCINE SPACE



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.

FIRST QUARTER IN BRIEF

MVA-BN smallpox vaccine

- BLA process on track

Fill and finish facility

- USD 44 million awarded by the U.S. Government for qualification, transfer and validation of process
- Progressing according to timeline and budget

RSV

- FDA discussions ongoing - to be finalized around mid-2019

Janssen partnership

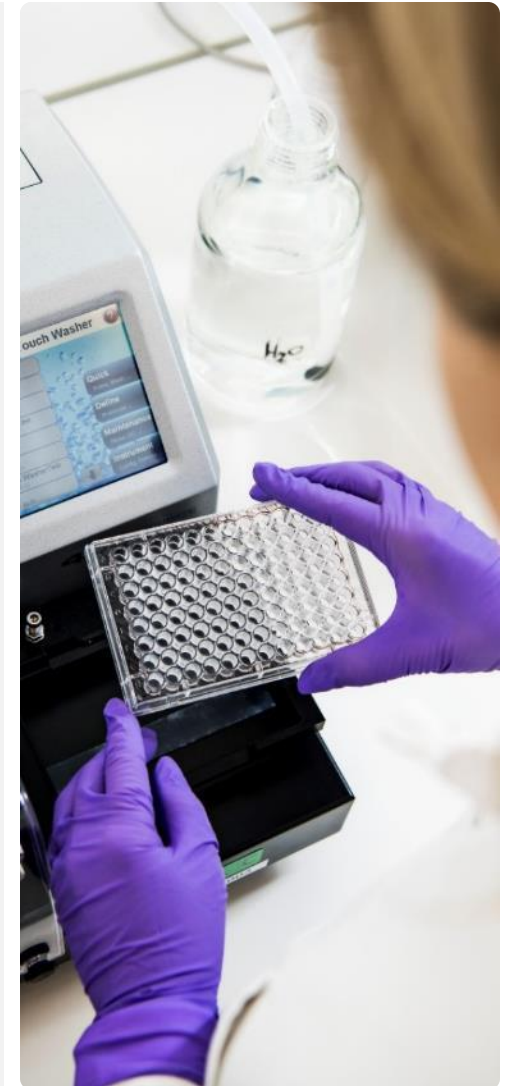
- Initiated Phase 1/2a study of therapeutic HPV vaccine
- WHO's advisory committee has updated their recommendations to include the Janssen/BN Ebola vaccine

Cancer immunotherapy

- Phase 2 trial of BN-Brachyury in chordoma enrolled stage 1 sooner than anticipated

Financials

- In line with expectations, full year guidance maintained



OUR VISION & STRATEGY

INVESTING FOR THE FUTURE

By 2023 we aspire to be a leading and profitable biotech company that through harnessing the power of the immune system will develop, manufacture and commercialize products for infectious disease and cancer

MAINTAIN global leadership of our smallpox vaccine business

- Finalize development of smallpox vaccine
- Secure broader sales

EXPAND and rapidly **ADVANCE** the pipeline of infectious disease programs

- Launch RSV vaccine
- Advance partnered programs
- Advance infectious disease pipeline

ESTABLISH a broad and deep cancer immunotherapy portfolio

- Explore combination therapies with vaccines and standard of care
- Explore more advanced combinations

EXPAND the commercial footprint and capabilities

- Take advantage of core manufacturing capabilities and capacity
- Build commercial infrastructure to drive profitable growth

A GLOBAL LEADER IN SMALLPOX VACCINES

- Strong presence and capabilities in the smallpox vaccine area
- MVA-BN is the only **non-replicating approved smallpox vaccine** in Europe and Canada
- U.S. government contracts awarded to-date valued at nearly USD 1.8 billion

THE PAST

- 22 clinical trials completed including two Phase 3 studies
- Approved in the U.S. for emergency use
- 28 million doses stockpiled for immune compromised - now expired
- BLA submitted

THE PRESENT

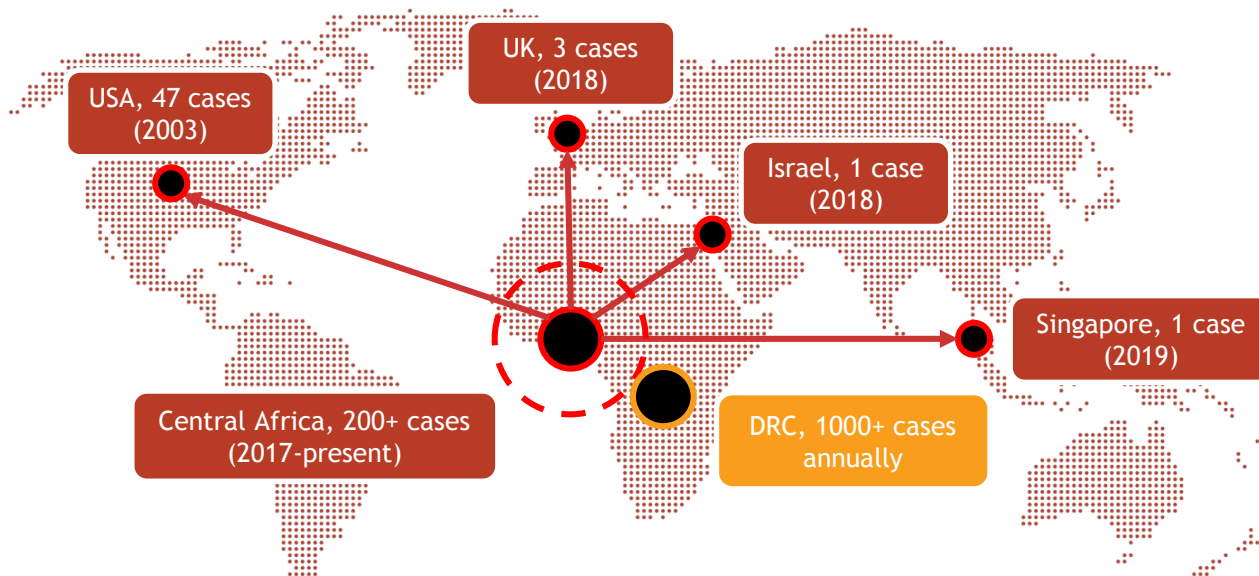
- Bulk vaccine worth USD 333 million produced to-date and stored for future fill and finish
- Approval expected in Q3 2019
- Priority Review Voucher to be sold
- Initiation of Phase 3 with freeze-dried vaccine imminent
- Finalizing construction of fill and finish facility

THE FUTURE

- USD 299 million in secured future revenue from completion of 13M freeze-dried doses
- 10-year contract with additional procurement options
- Post-approval opportunities beyond stockpiling according to existing guidelines
 - Military personnel
 - Healthcare workers

MONKEYPOX - AN EMERGING THREAT?

- Recent cases of **human monkeypox** in the U.K., Israel and Singapore highlight the need for preparedness plans; update of stockpiles with safest alternatives and **vaccination of first line responders**
 - Recent cases outside Africa all relate to current Nigeria outbreak
 - CDC-sponsored study of MVA-BN ongoing in DRC in 1,000 healthcare workers at-risk
 - U.K. authorities chose IMVANEX* over currently stockpiled, replicating smallpox vaccines for vaccination of healthcare workers

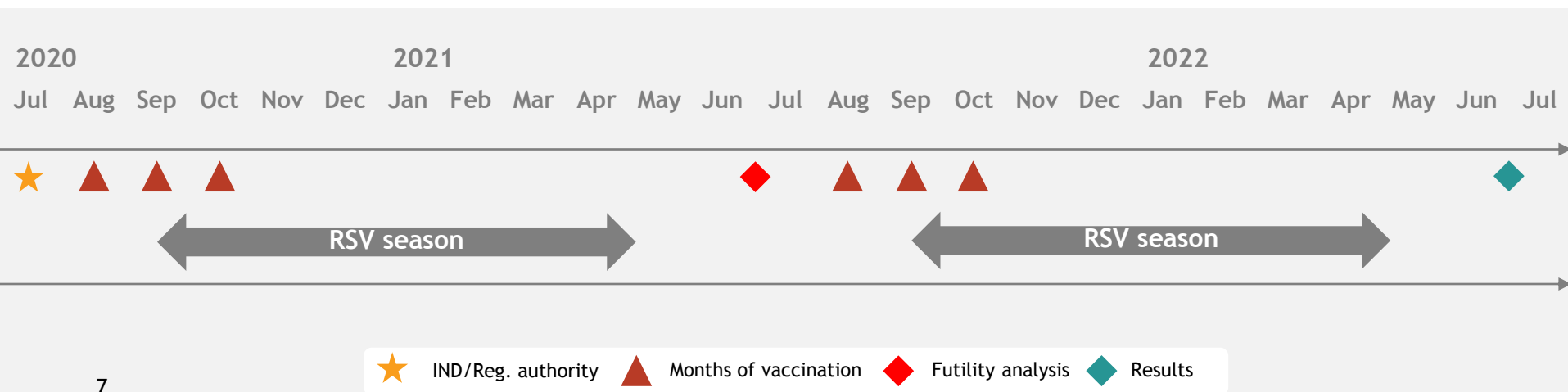


Monkeypox

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

RSV PHASE 3 CONSIDERATIONS

- Ongoing dialogue with the FDA regarding requirements for licensure of MVA-BN RSV
- Trial design to be finalized around mid-2019
- Current Phase 3 considerations:
 - Phase 3 in 12,000 - 18,000 depending on statistical plan to be agreed with the FDA
 - Study will start in 2020
 - Looking to conduct a Phase 3 over 2 RSV seasons including a futility analysis after season 1
 - Estimated Phase 3 trial cost: USD 80-120 M

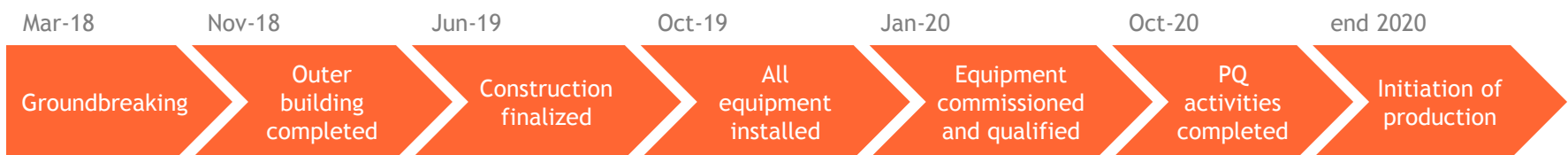


INVESTING FOR THE FUTURE



- Fill and finish facility
 - Up to 8M freeze-dried & 40M liquid doses per year
- Expands our manufacturing capability
 - Key driver in securing higher smallpox revenues in the years to come
- Support new partnerships
 - Launch RSV
 - Licensing of pipeline assets
 - Manufacturing for partners/collaborators

Project timeline



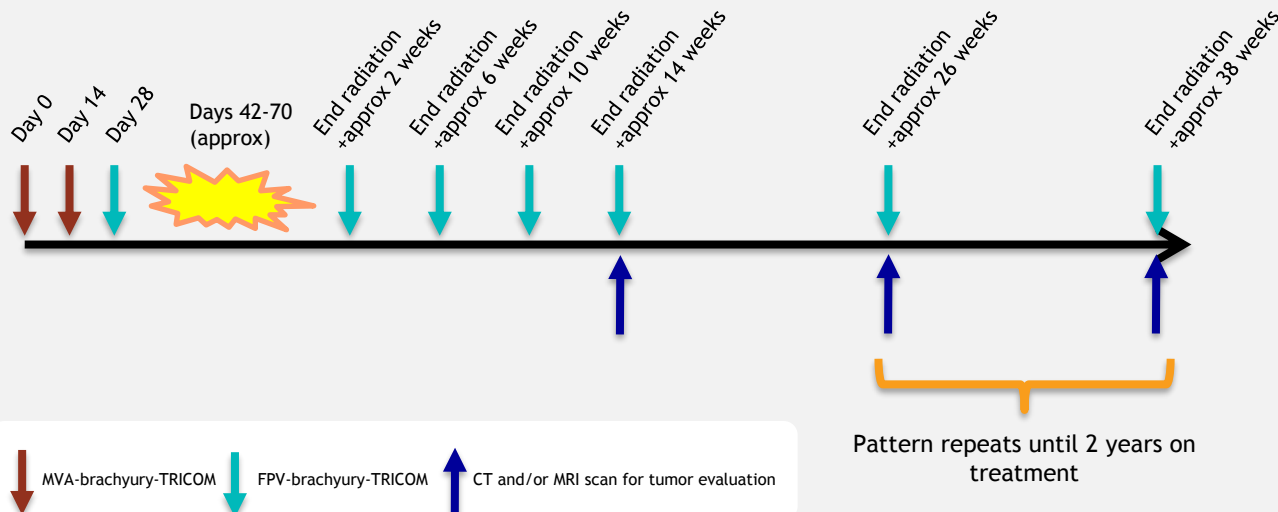
PIVOTAL TRIAL ONGOING IN CHORDOMA

ULTRA-ORPHAN CANCER WITH LIMITED TREATMENT OPTIONS

- Multi-site trial to assess the effectiveness of **BN-Brachyury** vaccine 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 **2 primer vaccinations** with **MVA-BN Brachyury** followed by **boosters** with (fowlpox virus) **FPV-Brachyury** and **radiation** therapy
- Establish if combo therapy results in a **clinically-meaningful ORR**

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%



STAGE 1 ongoing (N=10)

- Only proceed to stage 2 if at least 1 objective response occurs
- Patients enrolled between Nov-18 and Jan-19

STAGE 2 (N=19)

- ORR goal total = 4/29 patients (stage 1 + 2)

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**
- Patients receive **2 priming doses on MVA-BN-CV301** in four different injection sites, followed by **multiple boosters of FPV-CV301** at tapering intervals for the duration of checkpoint inhibitor therapy

Bladder cancer

CV301 + TECENTRIQ
(*atezolizumab*)

Primary Endpoint:
Objective Response Rate
(ORR)

N=68 (27 in stage 1)

Bavarian Nordic-sponsored
trial



Colorectal cancer

CV301 + OPDIVO
(*nivolumab*) & chemotherapy

Primary Endpoint:
Overall Survival (OS)

N=78

Sponsored by Rutgers
University



Bristol-Myers Squibb

Colorectal & Pancreatic

CV301 + IMFINZI
(*durvalumab*)

Primary Endpoint:
Progression Free Survival
(PFS)

N=52 (26 for each disease)

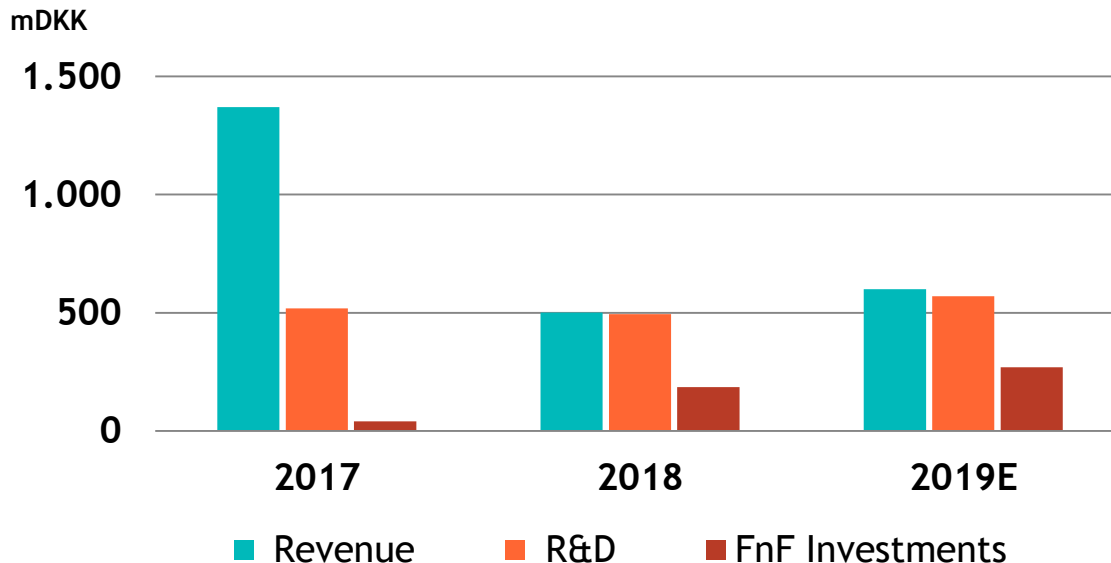
Sponsored by Georgetown
University

AstraZeneca 

INVESTING FOR THE FUTURE

RETURNING TO PROFITABILITY

- Adding value to the pipeline assets - R&D investments remain unchanged
- Collaborations in oncology ensure a balanced R&D spend
- Expanding manufacturing capabilities - transitional period of lower revenues
- Investments in Fill and Finish plant will peak in 2019 as construction will be finalized this year
- Financially well prepared for these investments



Partnerships



Collaborators



Bristol-Myers Squibb

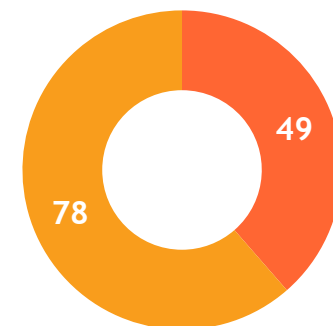


FINANCIAL RESULTS AND OUTLOOK

Full year guidance maintained

- Majority of 2019 revenue expected from second tranche of bulk smallpox vaccine contract (50 mUSD)
- R&D costs of approx. 570 mDKK (420 mDKK in P&L)
- Investments in FnF of approx. 270 mDKK (peak year)
- Sale of Priority Review Voucher has not been included in guidance

Revenue 3m, 2019 (mDKK)



■ MVA-BN, US

■ R&D Contracts

	3m 2019	FY2019E
	mDKK	
Revenue	127	600
EBIT	(104)	(360)
Cash preparedness	2,172	1,600

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

	3m 2019	FY 2019E
	mUSD	
	19	92
	(16)	(55)
	327	246

USD/DKK = 6.44

FINANCIAL POSITION

Break-down of financial position

- Strong financial position enabling continued execution of strategy
- Cash preparedness of DKK 2,172 million including unutilized credit lines

	mDKK		mUSD	
	3m 2019	FY2018	3m 2019	FY 2018
Securities, cash & equivalents	1,928	2,317	290	349
Less Repo assets	-	(247)	-	(37)
Unutilized credit lines	244	244	37	37
Total cash preparedness	2,172	2,314	327	348
Mortgage	27	28	4	4
EIB loan	372	372	56	56
Total debt (excl Repo liability)	399	400	60	60

USD / DKK = 6.64

2019 PRIORITIES AND GOALS



MAINTAIN global leadership of our smallpox vaccine business

- Initiate Phase 3 study of freeze-dried **MVA-BN**
- FDA approval of liquid-frozen **MVA-BN**
- Award of Priority Review **Voucher**

EXPAND and rapidly **ADVANCE** the pipeline of infectious disease programs

- Finalize **RSV** development plan
- Initiate Phase 1 dose finding study of **equine encephalitis virus** vaccine
- Initiate Phase 1/2a study of **HIV** vaccine with Janssen

ESTABLISH a broad and deep cancer immunotherapy portfolio

- Report initial ORR results from Phase 2 study of **BN-Brachyury** in chordoma
- Initiate Phase 1 intravenous administration of **BN-Brachyury**
- Initiate Phase 1 intra-tumoral administration of **CV301** in solid tumors
- Report initial ORR results from **CV301** and atezolizumab in bladder cancer

EXPAND the commercial footprint and capabilities

- Finalize construction of **fill and finish** facility

Q&A

