PANDEMIC PREPAREDNESS THROUGH COLLABORATION

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OUR MISSION: YEARS OF LIFE SAVED & QUALITY OF LIFE GENERATED

- Solving healthcare problems for the world
- Generating breakthroughs in science & technology
- Create partnerships to discover, develop and deliver new drugs, vaccines and solutions

Partnering with BARDA to address emerging pathogens: Ebola, Influenza, and others
OLD ENEMIES AND NEW THREATS

• **1918** – Deadliest *Influenza* pandemic in modern history
• **1975** – *Ebola* virus discovered
• **1983** – *HIV* virus identified
• **2016** – *Zika* outbreak, first confirmed outside of Africa
SIGNIFICANT GLOBAL BURDEN & MAJOR SECURITY THREAT

• **Influenza** – a continuing global security threat

• **Ebola** – a continuing epidemic threat for Africa and the world.

• **Zika** – a new devastating global disease with significant impact on new born babies & their families
SIGNIFICANT INNOVATION NEEDED TO MEET NEW CHALLENGES

• Why this is urgent:
  – Current treatments not optimal
  – Preemption is the best strategy

• We bring industry expertise & breakthrough innovations with strong track record in HIV, TB, HCV & other ID

• We have core technology platforms applicable to the challenges:
  – PER.C6® cell line
  – AdVac® to address diseases such as HIV, RSV and Zika
OUR FIRST SUCCESSFUL PARTNERSHIP: RESPONDING TO THE GLOBAL EBOLA CRISIS

- The 2014 Ebola crisis caught the world off guard
- Multiple stakeholders sprang into action, broad collaboration
- Accelerated the development of a prime-boost vaccine
- Multiple clinical trials on parallel tracks
- Scaled up production: 2M doses
EBOLA VACCINE: NONCLINICAL POC AND IMMUNOBRIDGING

- Heterologous prime-boost to protect against Ebola

- Proof of concept in NHP:
  - Ad26.ZEBOV/MVA-BN-Filo regimen protects against Ebola in stringent NHP challenge model at clinical dose

- Prediction of clinical benefit in absence of efficacy data to support licensure
  - Infer human clinical benefit by immunobridging
EBOLA REGIMEN: ON THE WAY TO LICENSURE

• Development
  – 11 clinical trials enrolled >4,000 subjects, now enrolling children
  – Stability profile compatible with current supply chain characteristics
  – Submission of Emergency Use Assessment and Listing to WHO

• Phase 1 Results
  – Appears safe and well tolerated
  – Strong antibody responses that persist at high levels for at least one year
EBOLA REGIMEN: ON THE WAY TO LICENSURE

- **Next steps:** Pre-EUA & filing of prophylactic vaccine for adult indication
  - Unblinding of phase 2 and 3 studies and Immunobridging
  - Manufacturing Process Performance Qualification
  - Lot-to-lot consistency trial
PANDEMIC INFLUENZA: “THE MOST FEARED SECURITY THREAT”

• Approaching 100 year anniversary of 1918 flu pandemic

• Major progress made with annual vaccinations, but flu continues to have major impact:
  – 1 billion cases; 300,000-500,000 deaths annually worldwide
  – 10-20% of population in developed countries infected each season

• Risk of serious complications especially high in very young and elderly

• Viruses circulating in wild birds may cross the species barrier to humans

• Resistance emerging to current standard of care

LONG-TERM PARTNERSHIP BETWEEN BARDA & JANSSEN (OTA) ESTABLISHED IN 2017

• Build on Janssen and BARDA’s established partnership in influenza with pimodivir
• Investing equally to advance extensive portfolio of influenza medicines & vaccines
  – Influenza PA endonuclease inhibitor, Phase 2a
  – Influenza multi-domain antibody, preclinical
  – Universal influenza vaccine, preclinical
  – An early stage discovery/development program to advance new targets for potential emerging pathogens of public health concern
RACING TO STOP ZIKA

• Zika caught the world off-guard; declared a public health emergency
• 84 countries and territories reporting mosquito-related Zika virus transmission
• Janssen collaboration with Harvard’s Beth Israel Deaconess Medical Center (BIDMC) to advance an investigational Zika vaccine
FIRST STEPS TOWARD A ZIKA VACCINE

• Vaccine candidate induces durable neutralising antibody responses: 100% of immunized Rhesus macaques were protected one year later

• Protection in mice was maintained, and shown not to depend on flavivirus pre-vaccination status

• Janssen Ad26 Zika vaccine, with similar insert, confirmed 100% protection in Rhesus macaques

• Leveraging the PER.C6® – Ad 26 platform: from concept to CTM release in 12 months
BARDA AND J&J: 
ENABLING JOINT SUCCESS

• Joint success in advancing vaccine platforms for influenza and Ebola,
• Combined resources and expertise allow for quick response to urgent challenges and pandemic preparedness
TOGETHER, WE CAN BEAT THESE ENEMIES AND CREATE A HEALTHIER WORLD