

**Janssen Ad26/PER.C6<sup>®</sup> based COVID-19 (SARS-CoV-2) vaccine candidate**

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Picture: a representation of a coronavirus

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**Janssen Vaccines – our ambition**

Establish a leadership position in transformational vaccines that are first and/or best in class in areas of high unmet medical need

Halt HIV

Prevent RSV

Respond to global pathogens

Prevent MDR bacterial infections

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**SARS-CoV-2 virus**

- A Beta coronavirus, like MERS and SARS
- 75% genetic homology with SARS
  - Use of human ACE2 receptor, like SARS
- 95% genetic homology with bat-coronaviruses

**Insights in SARS**

- The SARS-CoV-2 enters cells through binding its spike protein to the ACE2 receptor on cells
- Experimental SARS vaccines which induce neutralizing antibodies targeting the spike protein (present on the envelope of the virus) can protect animals from lethal challenge
- Several candidate vaccines predisposed for 'enhanced respiratory disease' (ERD) in vaccinated animals with breakthrough infections
  - Very similar to what was observed historically for a 'whole virus inactivated – alum adjuvanted' RSV vaccine in children where it was shown to be linked to a Th2-skewed immune response; not seen for vaccines driving Th1 pathways
  - Similar association between SARS vaccine associated ERD and vaccine elicited Th2 skewed immune response

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**Proprietary AdVac<sup>®</sup> and PER.C6<sup>®</sup> technology platforms are at the core of the Janssen COVID-19 vaccine candidate**

PER.C6 <sup>®</sup> cell line	AdVac <sup>®</sup>
<ul style="list-style-type: none"> <li>• Human immortalized cell line, which can be grown at high cell density, serum free</li> <li>• High yields (if vaccine doses) with small footprint – resulting in lower capex and lower COGs</li> <li>• Formulation know-how has resulted in competitive thermostability profile</li> <li>• Market authorization for PER.C6<sup>®</sup> derived product Rekovite<sup>®</sup> (Ferring)</li> </ul>	<ul style="list-style-type: none"> <li>• Induction of robust, durable immune responses – Humoral and cellular</li> <li>• Characterization of humoral immune responses reveals unique features (ADCC, ADCP, ADCC...) in addition to neutralization</li> <li>• Extensive clinical experience with Janssen Ad26-based vaccines (&gt;40,000 subjects vaccinated) show these to be safe and well-tolerated</li> </ul>
<ul style="list-style-type: none"> <li>• Platform concept:               <ul style="list-style-type: none"> <li>- Plug and Play</li> <li>- Fast from concept to First-in-Human (FIH)</li> <li>- Fast high output delivery' leveraging established platform process</li> </ul> </li> </ul>	

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**Key attributes of Janssen vaccine platform**

- AdVac<sup>®</sup> vector technology: potent, long-lasting cellular and humoral immunity
- Low or no risk of "Enhanced Respiratory Disease"
- Well-tolerated safety profile >67,000 people, and absence of any safety signal
- PER.C6<sup>®</sup> cell line: high yields, scalable, fully industrialized
- Favorable thermostability profile (> 2 years at 2-8°C)
- Distribution using existing infrastructure

Key attributes of Prioritization WHO	Vectored	DNA	RNA	J&J Vaccine
1 dose regimen	✓	✓	✓	✓
Neutralizing antibodies	✓	✓	✓	✓
Proven strategy	✓	✓	✓	✓
Cytokine CRM response	✓	✓	✓	✓
Risk of enhancement ↓	✓	✓	✓	✓
Speed of development	✓	✓	✓	✓
Capability to scale up	✓	✓	✓	✓
Duration of immunity	✓	✓	✓	✓
Vaccine stability	✓	✓	✓	✓
Cost/dose	✓	✓	✓	✓

✓ Fulfilled according to WHO ✓ Further based on literature data ✓ Other validated (proof of) manufacturability of relevant data ✓ Tested up to large scale production

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**Clinical Experience with Janssen Ad26-based vaccines >67,000 subjects vaccinated (as of 27 March 2020)**

46 completed and ongoing studies

RSV, HIV, Ebola, Malaria, RSV, Filovirus, Zika, HPV

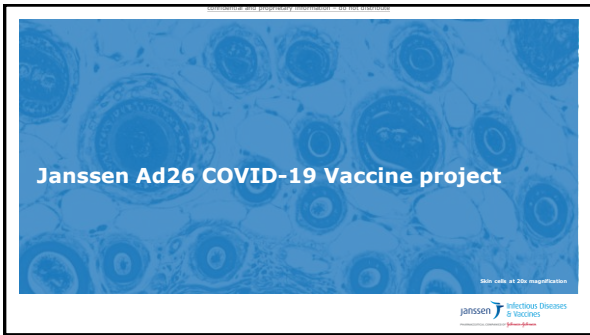
- Adults
- Elderly
- HIV+ adults
- Pregnant and breastfeeding women
- Children (1-17 years of age)
- Infants (4-11 months of age)
- 1x10<sup>8</sup> to 1x10<sup>11</sup> vp per dose

- Ad26-based vaccines are well tolerated
- Mostly mild to moderate AEs of rapid onset and short duration. Fever is not a prominent AE
- No significant safety issues have been identified and no safety signals have been detected

Countries: Australia, Brazil, Belgium, Burkina Faso, Canada, Côte d'Ivoire, DRC, Finland, France, Gabon, Kenya, Liberia, Malawi, Mali, Mozambique, Nigeria, Poland, Rwanda, Senegal, Sierra Leone, South Africa, Spain, Sweden, Tanzania, Thailand, Uganda, UK/USA, Zambia, Zimbabwe

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**Johnson & Johnson Announces a Lead Vaccine Candidate for COVID-19; Landmark New Partnership with U.S. Department of Health & Human Services; and Commitment to Supply One Billion Vaccines Worldwide for Emergency Pandemic Use**

*Johnson & Johnson and BARDA Together Commit More than \$1 Billion to Novel Coronavirus Vaccine Research and Development; Company Expects to Initiate Phase 1 Human Clinical Studies of Vaccine Candidate at Latest by September 2020*

*Johnson & Johnson Will Establish New U.S. Vaccine Manufacturing Capabilities and Additional Production Capacity Outside the U.S. to Begin Production at Risk to Help Ensure Global Vaccine Supply*

**NEW BRUNSWICK, N.J., March 30, 2020 – Johnson & Johnson**

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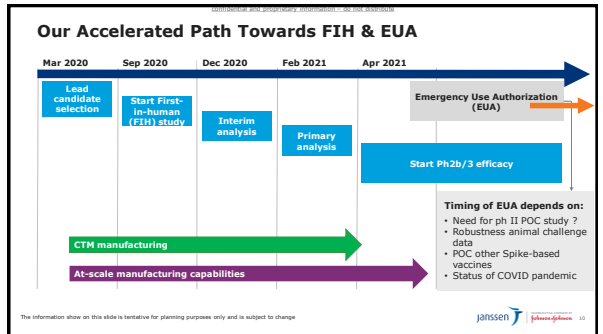
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**COVID-19 Discovery Vaccine Strategy**

- Aim is to induce Nabs and CMI targeting the Spike Protein of SARS-2-CoV
- Plasmid DNA vaccines for rapid comparison of several candidate transgenes
- Ad26 vectors containing these transgenes for preclinical and clinical development
- Vaccines are tested for immunogenicity and protective efficacy in animal models
- Animal data and manufacturability data will inform selection of vaccine candidate for clinical development

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**Vaccine Ad26 Manufacturing Facility – Leiden, the Netherlands**

- 2 x 1000L Bioreactors (disposable) with max. working volume of 900L
- Dedicated downstream processing line scaled to Bioreactor volumes
- Tech Transfer to other manufacturing sites planned

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**Janssen is well positioned to respond to the COVID outbreak, leveraging its platforms and capabilities**

- Collaborations with academic networks have been established to access the **best science and capabilities**, complementing our internal expertise
- We are engaged in intensified dialogue with Regulatory Agencies globally
- Leveraging our experience with our platforms we are optimistic that we will be able to **start a FIH COVID-2019 vaccine trial by Sept 2020**, with potential for rapid scale up
- Several at risk investments are made in parallel to enable the **fastest path forward**
- We are committed to expand **manufacturing capacity** in support of **worldwide deployment**

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