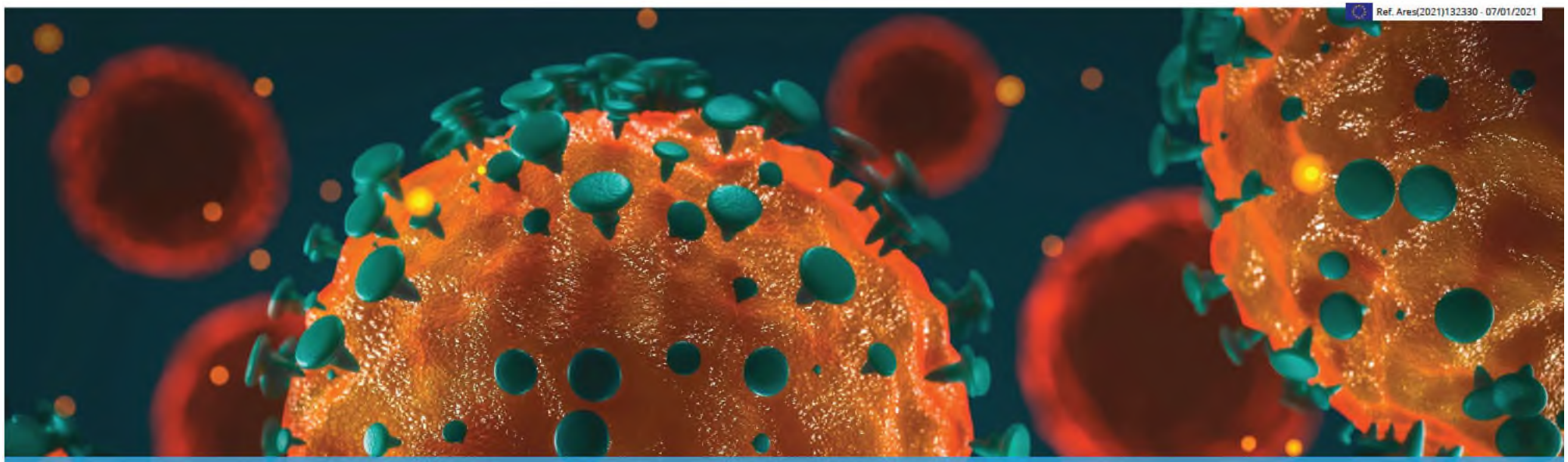

Janssen Ad26/PER.C6® based COVID-19 (SARS-CoV-2) vaccine candidate

Discussion document – strictly confidential

May 6th 2020

Pictured: a representation of a coronavirus

The information herein is being provided under the assurance that receivers will strictly maintain the confidentiality of the information and not further distribute to other parties

Janssen Infectious Diseases & Vaccines

PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Introductory statement

- The information included herein is provided in support of discussions with the European Commission. The information and estimates provided are for informational and discussion purposes only
- The information provided herein is considered Janssen Vaccines & Prevention B.V. trade secrets, commercial or financial information that Janssen Vaccines & Prevention B.V. customarily holds close and treats as confidential. The information is provided under the assurance that the European Commission and all of its agencies will strictly maintain the confidentiality of the information and not further distribute to other parties

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Agenda for today's discussion

- Janssen's COVID-19 vaccine development and further planning
- Update on Janssen Supply Chain global manufacturing planning

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Janssen's COVID-19 vaccine development and further planning

Skin cells at 20x magnification

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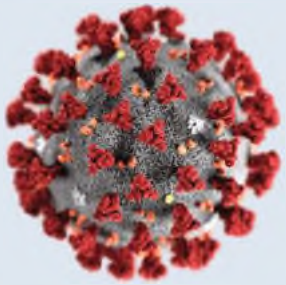
COVID-19: today's status (May 6th 2020)

Source: https://coronavirus.jhu.edu/map.html

SARS-CoV-2 virus



- Part of Beta Coronaviruses, 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[1]
- Experimental SARS Vaccines which induce neutralizing antibodies targeting the Spike protein (present on the envelope of the virus) can protect animals from lethal challenge[2,3]
- Several candidate vaccines predisposed for 'enhanced respiratory disease' (ERD) in vaccinated animals with breakthrough infections[4,5]
  - 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
  - Similar association between SARS vaccine associated ERD and vaccine elicited Th2 skewed immune response

1. Hoffmann M., et al., 2020. https://doi.org/10.1101/2020.01.31.929042.
2. Honda-Okubo Y et al. J Virol. 2015;89(6):2995-3007.
3. Bisht H et al. Proc Natl Acad Sci USA. 2004;101(17):6641-6646.
4. Tseng CT, Shrana F, Iwata-yoshikawa N, et al. PLoS ONE. 2012;7(4):e35421.
5. Iwata-yoshikawa N, Uda A, Suzuki T, et al. J Virol. 2014;88(15):8597-8614.

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

46 completed and ongoing studies

RSV, HIV, Ebola, Malaria, RSV, Filo, Zika, HPV

- Adults
- Elderly
- HIV+ adults
- Pregnant and breastfeeding women
- Children (1-17 years of age)
- Infants (4-11 months of age)
- $1x10^9$ to $1x10^{11}$ vp per dose

Countries:

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

- Ad26-based vaccines were 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 from the data available in the current adenoviral vaccine safety database

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Update on Janssen Supply Chain global manufacturing planning

Skin cells at 20x magnification

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