Janssen R&D response to Omicron VOC

- Janssen is rapidly moving forward with a multi-pronged approach to address the emergence of the Omicron variant

- First, we want to determine whether the current Ad26.COV2.S vaccine has cross-protection against Omicron.
  - Development of a pseudovirus assay to evaluate neutralization of Omicron by sera
    - from participants in clinical trials who received the primary regimen and homologous and heterologous booster doses
    - From NHP that received Ad26.COV2.S or Ad26.COV2.S.Beta
  - With partners, evaluating the effectiveness of the Ad26.COV2.S vaccine in an ongoing study (Sisonke 2) in South Africa (study start Nov 10, 2021)
    - Healthcare workers - ~477,000 enrolled in Sisonke (primary vaccination) who are offered a homologous booster dose (status Nov 29 : 142,000 boosted)
    - Effectiveness of a booster vs. single dose against hospitalizations, deaths, and infections

- Simultaneously, we are working to create an Ad26-based vaccine directed against the Omicron variant
  - CMC/Manufacturing and clinical development strategies are being developed at risk

- Regulatory guidance on testing of new variant vaccines urgently needed