

**Online Zoom meeting: 1000-11.30hrs**

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## Janssen

### Company Background

Janssen are part of Johnson & Johnson (J&J), one of the key areas they work is infectious diseases and vaccines. Janssen advised the UK-CAB at our last meeting (August 2019, see meeting overview below) that they were concentrating future pipeline on vaccines.

Janssen has been investigating a vaccine for the virus that causes COVID-19 (SARS-CoV-2). We have asked several questions relating to this work including: the impact on their HIV/infectious diseases pipeline; the cost and pricing of the vaccine etc. (see separate questions document).

### Pipeline

Janssen's injectable version of rilpivirine is currently going through the initial stages of the commissioning process with cabotegravir. ViiV are leading on this work as they developed the former drug which RPV is paired with for the long-acting treatment. If everything is approved we don't expect the LA drug to be available until late 2021/early 2022 at the earliest. NICE have taken over the commissioning of HIV treatments from the CRG and the LA CAB/RPV is the first of three drugs to undergo this new process.

Janssen has two large-scale studies investigating vaccines underway, Mosaico and Imbokodo.

### Overview of previous Company Meeting (August 2019)

- Discussed their collaborations with ViiV Healthcare, including the first licenced two-drug regime, branded Juluca, a fixed-dose combination of dolutegravir and rilpivirine.
- LA injectable with ViiV, cabotegravir and rilpivirine (currently at the first scoping stage of the new commissioning process in England via NICE)
- Implants and exploration of six-month formulations.
- UK-CAB were advised Janssen's current focus is vaccines. Development of a therapeutic vaccine is on-going with an aim to achieve long-term remission of HIV. In pre-clinical data three out of nine animals suppressed the virus after treatment interruption.
- Discussion of the Imbokodo study in southern Africa in women.
- Discussion of the Mosaico trial – aimed to have safety data by 2022/23
- CAB members also asked for updates around Janssen's work in TB and Hepatitis B (HBV). Janssen has a TB drug which works against multi-resistant strains of the infection, standard therapy is 48 weeks but they're studying 24-week therapy. This drug also works against other bacterial infections and further trials are being explored.
- Janssen's work in HBV is currently investigating a therapeutic vaccine to 'kick start' then clear out the infection. They are also researching RNA interference (RNAi). This research is important as whilst currently anyone taking TDF can suppress HBV it reactivates if you stop treatment.
- Preparations for a 'No deal Brexit' CAB members were advised Janssen were already prepared for March 2019.
- Discussion on clinical trials and representation of women.