Janssen publishes positive safety and efficacy data for single-dose COVID-19 vaccine

- Janssen publishes phase 3 trial data from study showing positive safety and efficacy results for its single-dose COVID-19 vaccine
- Vaccine shown to be 66% effective overall in preventing coronavirus in participants
- UK has secured 30 million doses with deliveries expected to arrive this year if approved by regulators

Janssen today (29 January) published positive data from the phase 3 studies of its single-dose Covid-19 vaccine candidate, showing it to be 66% effective overall in preventing coronavirus in participants. The data did not report any significant safety concerns relating to the vaccine, with no serious adverse events in vaccine recipients.

The UK has secured 30 million doses of Janssen's vaccine last summer, with deliveries expected to arrive in the second half of this year if approved for use by the Medicines and Healthcare products Regulatory Agency (MHRA), who will review and analyse the relevant data to see if the vaccine meets their strict standards of safety and effectiveness.

Today's results are for Janssen's single-dose study. Phase 3 trials for the company's two-dose regimen are ongoing worldwide, including in the UK at 16 National Institute for Health Research (NIHR) sites across the country. These trials involve more than 6,000 volunteers in the UK, some of whom were recruited from the NHS Vaccines Registry.

While a single dose of a safe and effective vaccine would offer a significant advantage during a global pandemic emergency, a two-dose schedule may have the potential to offer enhanced durability in some participants. Data from this multi-country study is expected later this year.

Business Secretary Kwasi Kwarteng said:

> This is yet more promising news from Janssen following last night's positive trial results from Novavax, and news this week that Valneva have started vaccine production in Scotland.
>
> Thanks to the life-saving work of our Vaccine Taskforce, the UK moved quickly to secure 30 million doses of Janssen's vaccine last summer. If this vaccine is authorised by our medicines regulator, we are set to receive the doses in the second half of this year.
>
> To date, the UK government has secured early access to a bumper portfolio of 367 million vaccine doses from seven separate vaccine

> developers, with Janssen’s vaccine the fifth to publish its phase 3 results.

The Janssen vaccine works in the same way as vaccine developed by Oxford and AstraZeneca and is designed to prompt an immune response including neutralising antibodies against the spike protein to eliminate the virus. Again similarly to the Oxford/AstraZeneca vaccine it can be safely stored and transported at standard refrigeration temperatures.

Health Secretary Matt Hancock said

> This is yet more good news from Janssen on vaccines. If this jab is approved this could significantly bolster our vaccination programme, especially as a single-dose vaccine.
>
> Once the full data has been submitted to the regulator they will consider the evidence to determine whether the vaccine meets robust standards of safety, effectiveness and quality.
>
> We are continuing to roll out vaccines as quickly as possible across the UK, with more than 7.4 million people given their first dose so far.

Vaccines Minister Nadhim Zahawi said:

> It is encouraging to see more positive news about vaccines coming through so quickly – this time from Janssen. Only a few months ago there were doubts over whether a Covid-19 vaccine would even be possible – now five companies have published good phase 3 results, three vaccines have been approved and over seven million people have received their first jabs.
>
> Vaccination is the way out of this pandemic, and I am once again grateful to all of the trial volunteers who have made these studies possible.

Through the Vaccines Taskforce, the UK has secured early access to 367 million doses of seven of the most promising vaccines so far. To date, the UK government has invested over £230 million into manufacturing a successful vaccine.

The UK was the first country in the world to procure, authorise and then deploy both the Oxford/AstraZeneca and Pfizer/BioNTech vaccines.

Production of the Oxford University/AstraZeneca vaccine started last autumn where the bulk of the vaccine for the UK is being made in Oxfordshire and Staffordshire, with filling into vials taking place in North Wales.

In total, more than 7.4 million people across the UK have now had a least one

dose of the vaccine.

- The Government’s vaccine supply and scheduled deliveries will fully support our target of offering a first vaccine dose to every person in the top four priority groups by mid-February.
- The members of the Joint Committee on Vaccination and Immunisation (JCVI) are independent experts who advise the UK on prioritisation at a population level for all vaccination and immunisation programmes; they have developed the prioritisation list of patient groups that is guiding the NHS vaccination programme and the committee keeps its advice under review and updates it as appropriate.
- The Government has a set process for approving any vaccine, with regulatory oversight provided by the MHRA. This involves MHRA approving a product licence after the applicant has generated appropriate data to demonstrate the quality, safety and efficacy of the vaccine.
- In total, the Government has procured 60 million doses of the Novavax candidate, the bulk of which will be manufactured in the UK if the vaccine is approved by regulators.

- Through the Government’s Vaccine Taskforce, the UK has secured early access to 367 million doses of 7 of the most promising vaccine candidates, including:

    - BioNTech/Pfizer – Approved – 40 million doses secured
    - Oxford/Astra Zeneca – Approved – 100 million doses secured
    - Moderna – Approved – 17 million doses secured
    - Novavax – Phase 3 – 60 million doses secured
    - Janssen – Phase 3 – 30 million doses secured
    - GSK/Sanofi – Phase 1/2 – 60 million doses secured
    - Valneva – Phase 1/2 – 60 million doses secured, with an option to acquire a further 130 million if the vaccine is proven to be safe, effective and suitable.
- The UK government has invested £127 million to fund a state-of-the-art manufacturing innovation centre in Braintree, Essex, in collaboration with the Cell and Gene Therapy Catapult, to accelerate the mass production of a successful Covid-19 vaccine in the UK. Due to open in December 2021, the centre will have the capacity to produce millions of doses of vaccines each month, ensuring the UK has the capabilities to manufacture both vaccines and advanced medicines, including for emerging diseases, far into the future.
- The government has also provided £4.7 million funding to the Catapult to ensure that the UK has the best skills and expertise in vaccine manufacturing and advanced therapies.
- The government has established a Rapid Deployment Facility with £8.75 million of investment which is manufacturing vaccines at scale.
- The government has also created the UK’s first dedicated Vaccine Manufacturing and Innovation Centre (VMIC) and accelerated its development with £93 million of investment. This investment will rapidly accelerate the construction of the facility, enabling us to bring it online sooner. It will also have expanded capability for advanced vaccine process development, fill and finish and bulk manufacture. In

addition, the facility’s capacity will be significantly increased to be able to respond to this pandemic. Once open, it will be able to manufacture 70 million vaccines doses in just 6 months – enough for the UK population. Located in Oxfordshire, the centre will be the UK’s first not-for-profit organisation established to develop and advance the mass production of vaccines. This will boost the UK’s long-term capacity against future viruses.