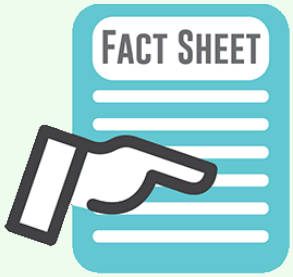

Janssen Covid 19 vaccine

Ad26.COV2.S [recombinant]

Fact Sheet

Live document - updated 20 June 2021

General Information

Phase 3 trial of the vaccine developed by global pharmaceutical company Janssen [a subsidiary of Johnson & Johnson] began 16 November 2020. It will initially involve 6000 volunteers from 17 sites across the UK including Belfast, Bristol, Cardiff, Dundee, Leicester, London, Manchester, Sheffield and Southampton. A further 24,000 volunteers are to be recruited from other countries. Phase 3 trials are designed to test the safety and effectiveness of drugs or vaccines in thousands of people. Like the Oxford vaccine, the Janssen candidate uses a weakened common cold virus called an adenovirus to deliver instructions for making the coronavirus's surface spike protein to our cells. Cells infected begin making the viral protein and expressing it on their surface, triggering an immune response. This includes the development of "memory" immune cells, which should protect against future coronavirus infections. However, whereas the Oxford vaccine is based on an adenovirus from chimpanzees, Janssen's vaccine uses a human adenovirus, which has been modified so it can no longer multiply or cause disease. The same virus forms the backbone of a recently approved Ebola vaccine, deployed during the 2019 outbreak in the Democratic Republic of the Congo. Janssen's vaccine has already undergone smaller phase 1 and 2 trials, and interim analysis of a single-dose study suggests that it induces a robust immune response and is generally well-tolerated. Assuming it proves safe and effective in larger trials, 30m doses could be made available to the UK by mid-2021.

Authorised for emergency use in individuals 18 years and older in the UK by MHRA 28 May 2021 under marketing authorisation Number P L G B 00242/0742.

Ad26.COV.S contains genetically modified organisms. List of Excipients:

- 2-hydroxypropyl-B-cyclodextrin [HBCD]
- Citric acid monohydrate
- Ethanol
- Hydrochloric acid
- Polysorbate 80
- Sodium Chloride
- Sodium hydroxide
- Trisodium citrate dihydrate
- Water for injection

Concerns regarding premature emergency authorisation for use in the human population

The following concerns have been drawn to the attention of MHRA.

- The experimental therapy [vaccine] was granted emergency authorisation 28 May 2021 by MHRA, prior to the **Public Assessment Report** [PAR] being finalised and published.
- Events of anaphylaxis have been reported.
- Not suitable for those suffering from an acute severe febrile illness or acute infection.
- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding has been observed. This includes severe cases of venous thrombosis at unusual sites such as cerebral venous sinus thrombosis [CVST], splanchnic vein thrombosis and arterial thrombosis concomitant with thrombocytopenia. Fatal outcomes have been reported. These cases occurred within the first three weeks following vaccination, and mostly in women under 60 years of age.
- Not suitable for individuals with a history of heparin-induced thrombocytopenia and thrombosis [HITT and HIT type 2].
- The efficacy, safety and immunogenicity of the vaccine has not been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy.
- On-going clinical trials to determine the duration of protection afforded by the experimental therapy [vaccine].
- No interaction studies have been performed. Concomitant administration of Covid 19 Vaccine Janssen with other vaccines has not been studied.
- Limited experience with the use of Covid 19 Vaccine Janssen in pregnant women.
- Not known whether Covid 19 Vaccine Janssen is excreted in human milk.
- Phase 3 study [COV3001] is ongoing. Medium and long-term impacts are not known.
- Adverse reactions are listed in attached document dated 28 May 2021 published on Gov.UK website.
- Further evidence is awaited by MHRA with annual reviews to be undertaken. This suggests ongoing experimentation on the human population.
- No genotoxicity and carcinogenicity studies have been undertaken

General Notes

Liability for damages

Janssen has been given indemnity in the UK, which means that people who suffer damage from the vaccine will not be able to sue the company. NHS staff providing the vaccine, as well as manufactures of the drug, are also protected.

Adverse Drug Reaction [ADR]

In October 2020 the MHRA posted a bid request stating that “For reasons of extreme urgency,” they seek “an Artificial Intelligence (AI) software tool to process the expected high volume of Covid-19 vaccine Adverse Drug Reaction (ADRs).” The bid goes on to explain that “it is not possible to retrofit the MHRA’s legacy systems to handle the volume of ADRs that will be generated by a Covid-19 vaccine,” and that this “represents a direct threat to patient life and public health.”

For latest information on ADR refer to MHRA "yellow card" data.

Concerns from medical / scientific profession

The following eminent members of the medical / scientific profession have serious concerns regarding vaccine safety and effectiveness. There are many others too numerous to list here.

Dr Andrew Kaufman,
Dr Hilde De Smet,
Dr Nils R Fosse,
Dr Elizabeth Evans,
Dr Mohammad Adil,
Dr Vernon Coleman,
Prof. Dolores Cahill,
Dr R Zac Cox,
Dr Anna Forbes,
Dr Ralf ER Sundberg,
Dr Johan Denis,
Dr Daniel Cullum,
Moritz von der Borch,
Dr Anne Fierlafijn,
Dr Tom Cowan,
Dr Kevin P. Corbett,
Dr Carrie Madej,
Dr Barre Lando,
Natural Nurse Kate Shemirani,
Pharmacist Sandy Lunoe,
Licensed Acupuncturist Boris Dragin,
Dr Piotr Rubas,
Dr Natalia Prego Cancelo,
Dr Rashid Buttar,
Dr Nour De San,
Dr Kelly Brogan,
Prof. Konstantin Pavlidis,
Dr Sherri Tenpenny,
Journalist Senta Depuydt,
Dr Heiko Santelmann,
Dr Margareta Griesz-Brisson,
Dr Mikael Nordforsa and
Dr Elke F. de Klerk

Definitions

Pharmacovigilance

Plays a key role in the healthcare system through assessment, monitoring, and discovery of interactions amongst drugs and their effects in humans.

Pharmacokinetics

Doses that are in a therapeutic range.

Toxicokinetics

Study of systemic exposure during toxicological experiments. Describes how a toxicant [i.e. a poison] enters the body and reaches a target tissue.

Teratogenicity

A teratogen is an agent that can disturb the development of an embryo or foetus. Teratogens halt the pregnancy or produce a congenital malformation [a birth defect]. Classes of teratogens include radiation, maternal infection, chemicals and drugs.

Genotoxicity

In vitro and in vivo tests designed to detect compounds that induce genetic damage e.g. damage to DNA.

Carcinogenicity

Ability or tendency to produce cancer.