Pfizer / BioNTech Vaccine

Abstract from Public Assessment Report [PAR] - 11 December 2020

mRNA vaccine BNT162b2

Notes

- First mRNA vaccine to be authorised for temporary supply and use in the human population.
- Remains under review as MHRA continues to receive data from company as it becomes available.
- Long-term follow-up efficacy and safety data to be assessed at a future date.
- No secondary pharmacology and safety pharmacology studies undertaken.
- No excretion studies have been conducted.
- No pharmacokinetic drug interaction studies have been conducted.
- No single dose toxicity studies have been undertaken.
- No toxicokinetic studies have been performed with the vaccine.
- No genotoxicity studies are planned for BNT162b2.
- No carcinogenicity studies with BNT162b2.
- A combined fertility and developmental study [including teratogenicity and postnatal investigations] in rats is ongoing.
- No prenatal and postnatal development, including maternal function studies have been done.
- No local tolerance studies have been done.
- No other toxicity studies have been done.
- No reproductive toxicity data is available.
- Not known whether the vaccine is safe for pregnant women. Use of vaccine in pregnancy will be investigated as part of pharmacovigilance plan.
- Women breast feeding should not be vaccinated. Not known whether BNT162b2 is excreted in breast milk.
- No environmental risk assessment available.
- Clinical study BNT162-01 ongoing [17 December 2020].
- Clinical study C4591001 ongoing [17 December 2020].
- Subjects with a history of severe adverse reaction associated with a vaccine and / or severe allergic reaction [e.g. anaphylaxis] were excluded from the study.
- Safety data for ongoing studies corresponding to longer follow-up will be submitted at a future date.
- 2 deaths reported in participants that received BNT162b2 in Phase 2 / 3 of study. C4591001: a participant died 3 days after dose 1. A participant experienced cardiac arrest 60 days after dose 2 and died 3 days later. There were 4 deaths in participants that received placebo in Phase 2 / 3.
- 126 participants reported Serious Adverse Event [SAE] during Phase 2 / 3 of study C4591001.
- 120 participants with HIV were included in the phase 3 part of study C4591001. Analysis of safety not yet available for this sub-group.
- Use of immunosuppressed individuals will be investigated as part of the pharmacovigilance plan.
- No data available on use with concomitant vaccines, including influenza vaccines.
- Long-term real-world data on vaccine effectiveness not available.

Supplementary Note

The following eminent members of medical / scientific profession have serious concerns regarding vaccine safety and effectiveness.

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.