FOI 23/025

23rd February 2023

Dear

Thank you for your request under FOIA, we sincerely apologise for the delay.

The study to which you refer to has concluded and did so shortly after authorisation.

Please note, the Summary of Product Characteristics for the COVID-19 mRNA Vaccine BNT162b2 (BNT162b2 RNA) [Pfizer/BioNTech COVID-19 vaccine] states:

Reproductive toxicity
Reproductive and developmental toxicity were investigated in rats in a combined fertility and developmental toxicity study where female rats were intramuscularly administered Comirnaty prior to mating and during gestation (receiving 4 full human doses that generate relatively higher levels in rat due to body weight differences, spanning between pre-mating day 21 and gestational day 20). SARS CoV-2 neutralizing antibody responses were present in maternal animals from prior to mating to the end of the study on postnatal day 21 as well as in foetuses and offspring. There were no vaccine related effects on female fertility, pregnancy, or embryo-foetal or offspring development. No Comirnaty data are available on vaccine placental transfer or excretion in milk

Please also refer to Page 50 of the EMA public assessment report (EPAR) which corresponds to the this same study: https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf. This vaccine is authorised / supplied under the Reliance Route authorisation and therefore, we are referring you to details in the EPAR.

Therefore, in answer to your questions:

When will results from this study be available?

A. These are available on page 50 of the EPAR provided above.

How will the results be made available to the general public?

A. As explained above (study findings already published in the EPAR).

You may also be interested in the below, which based on human studies (rather than data obtained from animal studies).

“The task force undertook a detailed review of several studies involving around 65,000 pregnancies at different stages. The review did not find any sign of an increased risk of pregnancy complications, miscarriages, preterm births or adverse effects in the unborn babies following mRNA COVID-19 vaccination. Despite some limitations in the data, the results appear consistent across studies looking at these outcomes.”

Reference: https://www.ema.europa.eu/en/news/covid-19-latest-safety-data-provide-reassurance-about-use-mrna-vaccines-during-pregnancy

If you have a query about the information provided, please reply to this email.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely

MHRA Customer Service Centre

Medicines and Healthcare products Regulatory Agency
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