AstraZeneca

Confidential

9th March 2021

COVID-19 Vaccine AstraZeneca

To Whom It May Concern

AstraZeneca has been informed of three Adverse Event cases of thromboses/embolism in Austria, for individuals who had recently received *COVID-19 Vaccine AstraZeneca.* In one of the cases, the outcome was fatal.

Hereby an update on the current AZ investigation:

QUALITY of the RELEVANT BATCHES

The following two batches are the subject of an investigation: batches ABV5300 and ABV3025.

A GMP investigation has been completed regarding the two batches. No issues or events have been found that could have an impact on product quality, safety or efficacy.

The batches have been supplied across most of Europe.

SAFETY ASSESSMENT

The assessments of the three cases are in progress. AstraZeneca will include a summary of these assessments in the AZD1222 COVID-19 Vaccine Monthly Summary Safety Report, which is due for submission on 15 March 2021.

For your information, the Austrian Federal Office for Safety in Health Care (BASG) has published the following statement on their webpage in regards to the first 2 events:

Currently, there is no evidence of a causal relationship with vaccination. Based on the known clinical data, a causal relationship cannot be established, as thrombotic events in particular are not among the known or typical side effects of the vaccine in question. According to current knowledge, the clinical data do not show any worrying data or signals in this respect compared to placebo. The immediately initiated international analysis of side effect reports also shows no accumulation of similar case reports so far (message brief 07/03/2021).

https://www.basg.gv.at/en/market-surveillance/official-announcements/detail/zwischenfaelle-nach-impfung-mit-covid-19-impfstoff-von-astrazeneca

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CONCLUSION

In summary, based on the assessment to date and the quality review of the batches, ABV5300 and ABV3025, AstraZeneca is not recommending any in-market actions and proposes that these batches continue to be distributed and administrated.

Best Regards,

AstraZeneca EU Qualified Person for Pharmacovigilance