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Vaxzevria showed no increased incidence of thrombosis with thrombocytopenia after second dose

PUBLISHED28 July 2021

28 July 2021 07:00 BST

Incidence rates were comparable to those among unvaccinated individuals

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Analysis of rare cases from global safety database published in The Cookies Lancet

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Rates of the very rare clotting disorder, thrombosis with thirombocytopenia syndrome (TTS), following a second dose of *Vaxzevria* are comparable to the background rate in an unvaccinated proproletion.+

The data, published in <u>The Lancet</u> today, demonstrated the estimated rate of TTS following a second dose of *Vaxzevria* was 2.3 per million vaccinees, comparable to the background rate observed in an unvaccinated population. It was 8.1 per million vaccinees after the first dose. The rate after the second dose is comparable to background rates observed in unvaccinated populations.

Sir Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "Vaxzevria is effective against all severities of COVID-19 and it plays a critical role in combatting the pandemic. Unless TTS was identified after the first dose, these results support the administration of the two-dose schedule of Vaxzevria, as indicated, to help provide protection against COVID-19 including against rising variants of concern."

The analysis was conducted using AstraZeneca's global safety database, which captures all spontaneously reported adverse events from real-world use of its medicines and vaccines worldwide. Reported cases of TTS globally were included up to the cut-off date of April 30 occurring within 14 days of administration of the first or second dose of *Vaxzevria*.

The results are in line with recent reports in the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Report, the UK system for collecting and monitoring information on safety concerns, which also show low rates of TTS after a second dose.²

No specific risk factors or definitive cause for TTS following COVID-19 vaccination have been identified and AstraZeneca continues to perform and support ongoing investigations of potential mechanisms. Furthermore, these very rare events can be avoided when symptoms are identified and treated appropriately.³

Vaxzevria, formerly AZD1222

Vaxzevria was co-invented by the University of Oxford and its spin-out company, Vaccitech. It uses a replication-deficient chimpanzee viral vector based on a weakened version of a common cold virus (adenovirus) that causes infections in chimpanzees and contains the genetic material of the SARS-CoV-2 virus spike protein. After vaccination, the surface spike protein is produced, priming the immune system to attack the SARS-CoV-2 virus if it later infects the body.

The vaccine has been granted a conditional marketing authorisation or emergency use in more than 80 countries across six continents. More than 800 million doses of COVID-19 Vaccine AstraZeneca have been supplied to more than 170 countries worldwide, including more than 100 countries through the COVAX Facility.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of

prescription medicines in Oncology, Rare Diseases and BioPharmaceuticals, including Cardiovascular Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts

For details on how the Investor Relations Team, please the Investo

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- 1 July Update. Available at: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting
- 3. Bussel, J.B., et al. (2021) Thrombosis with Thrombocytopenia Syndrome (also termed Vaccine-induced Thrombotic Thrombocytopenia): https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

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