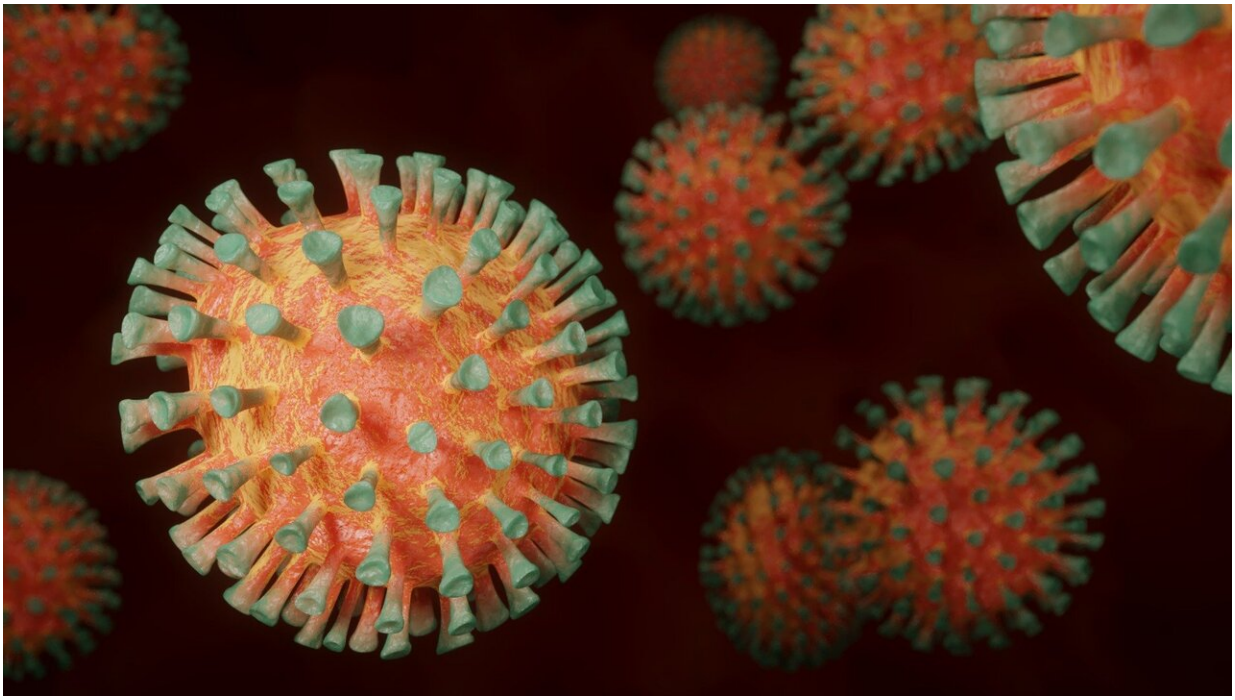
Medical Xpress

AstraZeneca files for EU vaccine approval

January 12 2021



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AstraZeneca and Oxford University have applied for authorisation for their coronavirus vaccine in the EU with a decision possible by January 29, the European Medicines Agency said on Tuesday.

The jab would be the third available for the 27-nation European Union after the Pfizer-BioNTech and Moderna drugs, as the bloc struggles to speed up the rollout.

"EMA has received an application for conditional marketing authorisation for a COVID-19 vaccine developed by AstraZeneca and Oxford University," the Amsterdam-based regulator said in a statement.

The EMA said its assessment would "proceed under an accelerated timeline".

"An opinion on the marketing authorisation could be issued by 29 January... provided that the data submitted on the quality, safety and efficacy of the vaccine are sufficiently robust and complete," it said.

The EU and the EMA have been under pressure to speed up approval of new vaccines against the virus, which has claimed the lives of more than 620,000 people across the continent.

European Commission chief Ursula von der Leyen hailed the application by Oxford-AstraZeneca as "good news".

"Once the vaccine receives a positive scientific opinion, we will work full speed to authorise its use in Europe," she said on Twitter.

The Oxford-AstraZeneca jab is cheaper to produce than its rivals, and easier to store and transport than the Pfizer-BioNTech vaccine in particular, which requires ultra-low freezing temperature.

It is based on a weakened version of a common cold virus (adenovirus) in chimpanzees which has been genetically changed to stop COVID-19 replicating in humans.

Oxford-AstraZeneca has previously been criticised over a lack of clarity and transparency on trials that had shown varying outcomes in the jab's efficiency.

Initial large-scale trials in which volunteers in the UK and Brazil were given two full doses showed 62 percent effectiveness.

For volunteers who received a half-dose first and then a full dose one month later, however, the vaccine was found to have 90 percent efficacy.

The EMA said it had already been reviewing data from "four ongoing clinical trials" in Britain, Brazil and South Africa.

"Additional scientific information on issues related to quality, safety and efficacy of the vaccine was also provided by the company at the request of (the EMA) and is currently being assessed," it added.

Citation: AstraZeneca files for EU vaccine approval (2021, January 12) retrieved 30 April 2024 from https://medicalxpress.com/news/2021-01-astrazeneca-eu-vaccine.html