COVID-19 Vaccine AstraZeneca authorised for use in the EU

PUBLISHED
29 January 2021

29 January 2021 20:30 GMT

AstraZeneca's COVID-19 vaccine has been granted a conditional marketing authorisation (CMA) in the European Union (EU) for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 18 years of age and older.

Following review of the application, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency based its positive opinion on data from a rolling review of trial data from the primary analysis of the Phase III programme led by the University of Oxford. Additional safety and efficacy data for the vaccine will continue to accumulate from ongoing clinical trials and is expected to be published in the coming weeks.

The CHMP recommends two doses of *COVID-19 Vaccine AstraZeneca*, formerly AZD1222, to be administered at a four- to 12-week interval in people aged 18 years and older. This dosing regimen was shown in clinical trials to be safe and effective in preventing symptomatic COVID-19, with no severe cases and no hospitalisations more than 14 days after the second dose.

AstraZeneca is working with the EU following the approval of a CMA for active immunisation to begin across member states.

Pascal Soriot, Chief Executive Officer, said: "Today's approval underscores the value of AstraZeneca's COVID-19 vaccine, which is not only effective and well tolerated, but also easy to administer and, importantly, protects fully against severe disease and hospitalisations. We are deeply grateful to Oxford University, participants in the clinical trials and AstraZeneca colleagues for their unwavering commitment to providing this lifesaving vaccine to millions of Europeans."

Professor Andrew Pollard, Director of the Oxford Vaccine Group and Chief Investigator on the Oxford vaccine trials, said: "The approval by the European Commission is an important milestone in extending access to the Oxford/ AstraZeneca vaccine in our region and providing further endorsement that, after the rigorous scrutiny of regulators, the vaccine can be used to help protect populations from the coronavirus pandemic."

AstraZeneca continues to work with regulatory authorities around the world to support their ongoing rolling reviews for emergency supply or conditional approval during the health crisis. AstraZeneca is also seeking Emergency Use Listing from the World Health Organization for an accelerated pathway to vaccine availability in low-income countries.

The vaccine can be stored, transported and handled at normal refrigerated conditions (two-eight degrees Celsius/36-46 degrees Fahrenheit) for at least six months and administered within existing healthcare settings.

AstraZeneca continues to engage with governments, international organisations and collaborators around the world to ensure broad and equitable access to the vaccine at no profit for the duration of the pandemic.

***COVID-19 Vaccine AstraZeneca*, formerly AZD1222**
COVID-19 Vaccine AstraZeneca 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.

CHMP's recommendation was based on an analysis of 23,745 participants aged 18 years and older, accruing 232 symptomatic COVID-19 infections from the UK and Brazil Phase III trials conducted by Oxford University.

The safety data published so far is from over 20,000 participants enrolled across four clinical trials in the UK, Brazil and South Africa. The publication in *The Lancet* confirmed that *COVID-19 Vaccine AstraZeneca* was well tolerated and that there were no serious safety events confirmed related to the vaccine. The participants were from diverse ethnic and geographic groups who were healthy or had stable underlying medical conditions.

In addition to the programme led by Oxford University, AstraZeneca is conducting a large trial in the US and globally. In total, Oxford University and AstraZeneca expect to enrol up to 60,000 participants globally.

The AstraZeneca COVID-19 vaccine has already been granted a CMA or emergency use in close to 40 countries, spanning four continents including in the EU, a number of Latin American countries, India, Morocco and the UK.

AstraZeneca
AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, 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 to contact the Investor Relations Team, please click here. For Media contacts, click here.

Adrian Kemp
Company Secretary
AstraZeneca PLC

Corporate and financial

AstraZeneca Websites

This website is intended for people seeking information on AstraZeneca's worldwide business. Our country sites can be located in the AZ Network.

Veeva ID: Z4-25396
Date of next review: August 2022

Resources

- All resources
- Open Innovation
- Externally sponsored scientific research
- Medical Information for HCPs
- US prescription assistance programmes
- Global clinical trials information
- Medicines
- Report a possible side effect

Quick links

- Media
- Investor Relations
- Partnering
- Careers
- Sustainability
- Modern Slavery Statement
- AZethics – Report A Concern
- Supplier information
- Social Media Community Guidelines

AstraZeneca