

AstraZeneca's COVID-19 vaccine authorised for emergency supply in the UK

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This announcement contains inside information

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Working with the UK government, first vaccinations to begin early in the New Year

Regulatory interactions continue around the world for next approvals

AstraZeneca's COVID-19 vaccine has been approved for emergency supply in the UK, with the first doses being released today so that vaccinations may begin early in the New Year.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has provided authorisation for emergency supply of *COVID-19 Vaccine AstraZeneca*, formerly AZD1222, for the active immunisation of individuals 18 years or older. The authorisation recommends two doses administered with an interval of between four and 12 weeks. This regimen was shown in clinical trials to be generally well-tolerated and effective at preventing symptomatic COVID-19, with no severe cases and no hospitalisations more than 14 days after the second dose.

AstraZeneca is working with Public Health England and National Health Service England to support the deployment and roll out of the vaccine in the UK, in line with the MHRA and the UK's Joint Committee on Vaccination and Immunisation dosing recommendation. The Company aims to supply millions of doses in the first quarter as part of an agreement with the government to supply up to 100 million doses in total.

Pascal Soriot, Chief Executive Officer, said: "Today is an important day for millions of people in the UK who will get access to this new vaccine. It has been shown to be effective, well-tolerated, simple to administer and is supplied by AstraZeneca at no profit. We would like to

thank our many colleagues at AstraZeneca, Oxford University, the UK government and the tens of thousands of clinical trial participants."

Matt Hancock, UK Secretary of State for Health and Social Care, said: "This is a moment to celebrate British innovation- not only are we responsible for discovering the first treatment to reduce mortality for Covid-19, this vaccine will be made available to some of the poorest regions of the world at a low cost, helping protect countless people from this awful disease. It is a tribute to the incredible UK scientists at Oxford University and AstraZeneca whose breakthrough will help to save lives around the world. I want to thank every single person who has been part of this British success story. While it is a time to be hopeful, it is so vital everyone continues to play their part to drive down infections."

Professor Andrew Pollard, Director of the Oxford Vaccine Group and Chief Investigator of the Oxford Vaccine Trial, said: "The regulator's assessment that this is an effective vaccine is a landmark moment, and an endorsement of the huge effort from a devoted international team of researchers and our dedicated trial participants. Though this is just the beginning, we will start to get ahead of the pandemic, protect health and economies when the vulnerable are vaccinated everywhere, as many as possible as soon possible."

The decision to approve the vaccine was taken under Regulation 174 of the Human Medicine Regulations 2012, which enables rapid emergency regulatory approvals to address significant public health issues such as a pandemic. This is the first authorisation for this vaccine.

The MHRA's decision was based on independent advice from its Commission on Human Medicines following a rolling review of trial data that included an interim analysis of the Phase III programme led by the University of Oxford. The data were also published in *The Lancet* on 8 December 2020.

Additional safety and efficacy data for the vaccine will continue to accumulate from ongoing clinical trials. AstraZeneca continues to work with regulatory authorities around the world to support their ongoing rolling reviews for emergency supply or conditional marketing authorisation 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- and middle-income countries.

AstraZeneca is working with its global partners to continue building manufacturing capacity of up to three billion doses of the vaccine globally in 2021 on a rolling basis, pending regulatory approvals. 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, multilateral organisations and collaborators around the world to ensure broad and equitable access to the vaccine at no profit for the duration of the pandemic.

AZD1222

AZD1222 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 interim analysis for efficacy was based on 11,636 participants accruing 131 symptomatic infections from the UK and Brazil Phase III trials conducted by Oxford University.

As announced on 23 November 2020, the primary efficacy endpoint based on a pooled analysis showed that the vaccine was effective (Overall efficacy was 70·4% (95·8% CI 54·8–80·6; 30 [0·5%] of 5807 vs 101 [1·7%] of 5829) at preventing symptomatic COVID-19 occurring more than 14 days after receiving two doses of the vaccine. A secondary efficacy endpoint of prevention of severe disease demonstrated no cases of severe infections or hospitalisations in the vaccine group.

The safety data published so far is from over 20,000 participants enrolled across four clinical trials in the UK and Brazil and South Africa. *The Lancet* publication confirmed that AZD1222 was well tolerated and that there were no serious safety events confirmed related to the vaccine. The participants were from diverse racial and geographic groups who are healthy or have stable underlying medical conditions. This analysis provides safety data on 74,341 person-months of follow-up after first dose (median 3.4 months) and 29,060 person-months of follow-up after two doses (median 2.0 months). The overall reported rates of serious adverse events were 0.7% in the vaccine group and 0.8% in the control group.

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.

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](https://www.astrazeneca.com) and follow the Company on Twitter @AstraZeneca.

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