News Release

15 February 2021 20:00 GMT

AstraZeneca COVID-19 vaccine authorised for emergency use by the World Health Organization

Emergency Use Listing granted to AstraZeneca and Serum Institute of India enabling global access to the vaccine

AstraZeneca's COVID-19 vaccine has been granted Emergency Use Listing (EUL) by the World Health Organization (WHO) for active immunisation to prevent COVID-19 in individuals 18 years of age and older, including those over 65.

The authorisation of *COVID-19 Vaccine AstraZeneca* manufactured by AstraZeneca, and *COVISHIELD* manufactured by Serum Institute of India (SII), enables global access to the vaccine during the pandemic.

The EUL allows for two doses of the vaccine to be administered at a four to 12-week interval. This 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. The WHO's Strategic Advisory Group of Experts on Immunization (SAGE) recommended a dosing interval of eight to 12 weeks. In addition, they also recommended use of the vaccine in countries where new variants, including the South African B1.351 variant, are prevalent.

AstraZeneca and SII will now work with the COVAX Facility to begin supplying the vaccine around the world, with the majority going to low and middle-income countries as quickly as possible. In the first half of 2021, it is hoped that more than 300 million doses of the vaccine will be made available to 145 countries through COVAX, pending supply and operational challenges. These doses will be allocated equitably according to the COVAX Allocation Framework.

Pascal Soriot, Chief Executive Officer, said: "Today's approval endorses that the vaccine can be used to help protect populations across the world, including adults over 65 years and in countries where different variants of the SARS-CoV-2 virus are in circulation. This is a huge step towards ensuring global access to our vaccine and helping us fulfil our public health commitment to broad and equitable access at no profit during the pandemic."

Adar Poonawalla, Chief Executive Officer, Serum Institute of India, said: "We have been waiting for this final milestone. I am happy and relieved that with the WHO's EUL we will be able to start the deliveries to African and other low and middle-income countries immediately. Countries with a large population must be protected as soon as possible."

AstraZeneca has committed to making its COVID-19 vaccine available to as many countries as possible and at no profit during the pandemic period. In June 2020, the Company announced a sub-licencing agreement with the SII to manufacture and supply up to one billion doses of the vaccine to low and middle-income countries.

The Company was the first global pharmaceutical company to join COVAX in June 2020. This global mechanism is working to accelerate the development, production and equitable access to new COVID-19 tools across the world for all participating countries, regardless of income level.

AstraZeneca's COVID-19 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.

***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.

The WHO approval was based on pooled analysis for efficacy from 11,636 participants aged 18 years and older, accruing 131 symptomatic COVID-19 infections from the UK and Brazil Phase III trials conducted by Oxford University.

Overall safety was based on an interim analysis of pooled data from four clinical trials conducted in the UK, Brazil and South Africa which included 23,745 participants aged 18 years or older. *COVID-19 Vaccine AstraZeneca* was well tolerated and 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.

AstraZeneca's COVID-19 vaccine has been granted a conditional marketing authorisation or emergency use in more than 50 countries, with the WHO EUL now accelerating the pathway to access in up to 145 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, 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.

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