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ASIA EDITION

AstraZeneca's COVID-19 vaccine receives EUA in the UK

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AstraZeneca's COVID-19 vaccine has been approved for emergency supply in the UK, with the first doses being released on 30 Dec 2020 so that vaccinations may begin early in the New Year.

The UK Medicines and Healthcare products Regulatory Agency (MHRA) has provided emergency use authorisation (EUA) authorization for *COVID-19 Vaccine AstraZeneca*, formerly AZD1222, for the active immunisation of individuals 18 years or older. The authorization recommends two doses administered with an interval of between four and 12 weeks. This regimen was shown in clinical trials to be safe 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.

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 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.