News Release

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AZD1222 Oxford Phase III trials interim analysis results published in *The Lancet*

Interim analysis showed vaccine is effective at preventing COVID-19, with no severe cases and no hospitalisations more than 21 days after first injection

Regulatory submissions underway to support approval

Results of an interim analysis of the Phase III programme conducted by Oxford University with AZD1222, peer-reviewed and published in *The Lancet* today, demonstrated that the vaccine is safe and effective at preventing symptomatic COVID-19 and that it protects against severe disease and hospitalisation. The interim analysis for efficacy was based on 11,636 participants accruing 131 symptomatic infections from the Phase III UK and Brazil trials conducted by Oxford University.

As announced on 23 November 2020, the primary efficacy endpoint of the programme statistical plan, based on the pooling of two dosing regimens, showed that the vaccine is 70.4% (95.8% CI: 54.8% to 80.6%) effective 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.

A further analysis of the efficacy regimens showed that when the vaccine was given as two full doses, vaccine efficacy was 62.1% (n=8,895; CI 41.0% to 75.7%), and 90.0% (n=2,741; CI 67.4% to 97.0%) in participants who received a half dose followed by a full dose.

Vaccine efficacy was also assessed on the secondary endpoint of early prevention of severe disease after the first dose. There were no hospitalisations or severe cases of COVID-19 more than 21 days after the first dose of the vaccine. Ten participants in the control group were hospitalised due to COVID-19, among whom two were assessed as severe, including one fatal case.

More data will continue to accumulate as part of the upcoming primary analysis and further follow-up, refining the efficacy reading and characterising vaccine efficacy over a longer period of time.

The safety data published so far is from over 20,000 participants enrolled across four clinical trials in the UK (COV001 and COV002), Brazil (COV003) and, in addition, from South Africa (COV005). *The Lancet* publication confirmed that AZD1222 was well tolerated and that there were no serious safety events 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 74,434 person-months of follow-up after first dose (median 3.4 months) and 29,097 person-months of follow-up after two doses (median 2.0). The overall

reported rates of serious adverse events were 0.7% in the vaccine group and 0.8% in the control group.

Professor Andrew Pollard, Director of the Oxford Vaccine Group and Chief Investigator of the Oxford Vaccine Trial, said: “Today, we have published the interim analysis of the Phase III trial and show that this new vaccine has a good safety record and efficacy against the coronavirus. We are hugely grateful to our trial volunteers for working with us over the past eight months to bring us to this milestone.”

Pascal Soriot, Chief Executive Officer, said: “Today’s peer-reviewed publication enables a full disclosure of the Oxford programme interim analysis. The results show that the vaccine is effective against COVID-19, with in particular no severe infections and no hospitalisations in the vaccine group, as well as safe and well tolerated. We have begun submitting data to regulatory authorities around the world for early approval and our global supply chains are up and running, ready to quickly begin delivering hundreds of millions of doses on a global scale at no profit.”

Submission of the data to regulatory authorities around the world has already begun, as part of their ongoing rolling reviews of the vaccine data for temporary use or conditional approval during this health crisis. The Company is also seeking Emergency Use Listing from the World Health Organization for an accelerated pathway to vaccine availability in low-income countries.

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

The Company is also making rapid progress in manufacturing with a capacity of up to 3 billion doses of the vaccine in 2021 on a rolling basis, pending regulatory approval. The vaccine can be stored, transported and handled at normal refrigerated conditions (2-8 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.

COV001

COV001 is a blinded, multi-centre, randomised, controlled Phase I/II trial assessing safety, immunogenicity and efficacy of AZD1222 in 1,077 healthy adults in five trial centres in the UK. Participants aged 18-55 years are randomised to receive one or two intramuscular doses of AZD1222 at $5x10^{10}$ viral particles or comparator, meningococcal vaccine MenACWY. Participants have blood samples drawn and clinical assessments for safety as well as immunogenicity at multiple timepoints up to one year post-vaccination. Weekly COVID-19 PCR testing is performed with retest at 3-5 days post-symptoms onset if the first sample is negative and 7 days after a positive PCR test.

COV002

COV002 is a single-blinded, multi-centre, randomised, controlled Phase II/III trial assessing the safety, efficacy and immunogenicity of AZD1222 in 12,390 participants in the UK. Trial participants to date are aged 18 years or over, who are healthy or have medically stable chronic diseases and are at increased risk for being exposed to the SARS-CoV-2 virus. Participants receive one or two intramuscular doses of a half dose (~2.5 $x10^{10}$ viral particles) or full dose (~$5x10^{10}$ viral particles) of AZD1222 or comparator, meningococcal vaccine MenACWY. Participants have blood samples drawn and clinical assessments for safety as well as immunogenicity at multiple timepoints up to one year post-vaccination. Suspected cases presenting with compatible symptoms were tested for virological confirmation by COVID-19 PCR. In addition, weekly swabbing are done for detection of infection and assessment of vaccine efficacy against infection.

COV003

COV003 is a single-blinded, multi-centre, randomised, controlled Phase III trial assessing the safety, efficacy, and immunogenicity of AZD1222 in 10,300 participants in Brazil. Trial participants to date are aged 18 years or over, who are healthy or have medically stable chronic diseases and are at increased risk for being exposed to the SARS-CoV-2 virus. Participants are randomised to receive two intramuscular doses of a full dose (~$5x10^{10}$ viral particles) of AZD1222 or comparator, meningococcal vaccine MenACWY as first dose and a saline placebo as second dose. Participants have blood samples drawn and clinical assessments for safety as well as immunogenicity at multiple timepoints up to one year post-vaccination. Suspected cases presenting with compatible symptoms were tested for virological confirmation by COVID-19 PCR.

COV005

COV005 is a blinded, multi-centre, randomised, controlled Phase I/II trial assessing the safety, efficacy, and immunogenicity of AZD1222 in 2,070 participants in South Africa. Trial participants are aged 18-65 years, who are living with or without HIV, are randomised to receive two intramuscular doses of AZD1222 at 5-7.5 $x10^{10}$ viral particles or saline placebo. Participants had blood samples drawn and clinical assessments for safety as well as immunogenicity at multiple timepoints up to one year post-vaccination. Regular COVID-19 PCR testing is performed up to one year post-vaccination.

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.

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.