News Release

Regulatory News Service

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AZD1222 US Phase III primary analysis confirms safety and efficacy

76% vaccine efficacy against symptomatic COVID-19

100% efficacy against severe or critical disease and hospitalisation

85% efficacy against symptomatic COVID-19 in participants aged 65 years and over

Positive high-level results from the primary analysis of the Phase III trial of AZD1222 in the US have confirmed vaccine efficacy consistent with the pre-specified interim analysis announced on Monday 22 March 2021.

These results have been presented to the independent Data Safety Monitoring Board. The primary analysis is pre-specified in the protocol and will be the basis for a regulatory submission for Emergency Use Authorization to the US Food and Drug Administration in the coming weeks.

This primary efficacy analysis included the accrual of 190 symptomatic cases of COVID-19 from the 32,449 trial participants, an additional 49 cases to the previously announced interim analysis. Participants were randomised on a 2:1 ratio between the vaccine and placebo group.

The primary endpoint, vaccine efficacy at preventing symptomatic COVID-19 was 76% (confidence interval (CI): 68% to 82%) occurring 15 days or more after receiving two doses given four weeks apart. In addition, results were comparable across age groups, with vaccine efficacy of 85% (CI: 58% to 95%) in adults 65 years and older. A key secondary endpoint, preventing severe or critical disease and hospitalisation, demonstrated 100% efficacy. There were eight cases of severe COVID-19 observed in the primary analysis with all of those cases in the placebo group.

The vaccine was well tolerated, and no safety concerns related to the vaccine were identified.

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: “The primary analysis is consistent with our previously released interim analysis, and confirms that our COVID-19 vaccine is highly effective in adults, including those aged 65 years and over. We look forward to filing our regulatory submission for Emergency Use Authorization in the US and preparing for the rollout of millions of doses across America.”

There were 190 cases in the primary analysis. There are 14 additional possible or probable cases to be adjudicated so the total number of cases and the point estimate may fluctuate slightly.

AstraZeneca will also submit the primary analysis for peer-reviewed publication in the coming weeks.

D8110C00001[1]

The US Phase III trial, called D8110C00001, was led by AstraZeneca and funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the office of the Assistant Secretary for Preparedness and Response (ASPR) at the US Department of Health and Human Services (HHS) in collaboration with the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND) and the Army Contracting Command, and the National Institute of Allergy and Infectious Diseases (NIAID), part of the US National Institutes of Health. The NIAID-supported COVID-19 Prevention Network (CoVPN) participated in the trial.

D8110C00001 is a randomised, double-blind, placebo-controlled multicentre Phase III trial assessing the safety, efficacy, and immunogenicity of AZD1222 compared to placebo for the prevention of COVID-19, in 32,449 participants across 88 trial centres in the US, Peru and Chile. Trial participants 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 and COVID-19 were randomised in a 2:1 ratio to receive two intramuscular doses of either 5 $x10^{10}$ viral particles of AZD1222 or saline placebo four weeks apart.

The pre-specified statistical analysis plan required at least 75 adjudicated cases at interim analysis, and at least 150 adjudicated cases at primary analysis.

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.

In May 2020, AstraZeneca received support of more than $1bn from BARDA for the development, production and delivery of the vaccine under an agreement with the US Department of Defense's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense. The Phase III D8110C00001 trial is part of this funding agreement.

The vaccine has been granted a conditional marketing authorisation or emergency use in more than 70 countries across six continents, and with the Emergency Use Listing granted by the World Health Organization this accelerates the pathway to access in up to 142 countries through the COVAX Facility.

BARDA, ASPR, HHS

HHS works to enhance and protect the health and well-being of all Americans, providing for effective health and human services and fostering advances in medicine, public health, and social services. The mission of ASPR is to save lives and protect Americans from 21st century health security threats. Within ASPR, BARDA invests in the innovation, advanced research

and development, acquisition, and manufacturing of medical countermeasures – vaccines, drugs, therapeutics, diagnostic tools, and non-pharmaceutical products needed to combat health security threats. The AstraZeneca vaccine candidate is one of six BARDA is supporting in development and manufacturing, and the third BARDA-supported SARS-COVD-2 vaccine supported to successfully complete a large Phase III trial. To learn more about BARDA's support for the COVID-19 pandemic response, visit medicalcountermeasures.gov.

JPEO-CBRND

As part of the Department of Defense, JPEO-CBRND protects the Joint Force by providing medical countermeasures and defense equipment against chemical, biological, radiological and nuclear (CBRN) threats. JPEO-CBRND's goal is to enable the Joint Force to fight and win unencumbered by a CBRN environment. JPEO-CBRND facilitates the rapid response, advanced development, manufacturing and acquisition of medical solutions, such as vaccines, therapeutics, and diagnostics, to combat CBRN and emerging threats such as COVID-19. To learn more about JPEO-CBRND's COVID-19 response, visit https://www.jpeocbrnd.osd.mil/coronavirus.

NIAID and the CoVPN

The CoVPN was formed by the NIAID at the US National Institutes of Health, part of the US Department of Health and Human Services, to respond to the global pandemic. Through the CoVPN, NIAID is leveraging the infectious disease and community engagement expertise of its existing research networks and global partners to address the pressing need for vaccines and antibodies against the SARS-CoV-2 virus. CoVPN will work to develop and conduct studies to ensure rapid and thorough evaluation of vaccines and antibodies for the prevention of COVID-19.

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.

References

1. Clinicaltrials.gov. A Phase III Randomized, Double-blind, Placebo-controlled Multicenter Study in Adults to Determine the Safety, Efficacy, and Immunogenicity of AZD1222, a Non-replicating ChAdOx1 Vector Vaccine, for the Prevention of COVID-19. [Online] Available at: https://clinicaltrials.gov/ct2/show/NCT04516746?term=NCT04516746&draw=2&rank=1. Last accessed: February 2021.

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