BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

AZD1222 US Phase III primary analysis confirms safety and efficacy

25 March 2021 | News

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.