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AstraZeneca vaccine meet primary efficacy endpoint in preventing COVID-19

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Two different dosing regimens demonstrated efficacy with one showing a better profile when tested on mildpatients

Positive high-level results from an interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing COVID-19, the primary endpoint, and no hospitalisations or severe cases of the disease were reported in participants receiving the vaccine. There were a total of 131 COVID-19 cases in the interim analysis.

One dosing regimen (n=2,741) showed vaccine efficacy of 90% when AZD1222 was given as a half dose, followed by a full dose at least one month apart, and another dosing regimen (n=8,895) showed 62% efficacy when given as two full doses at least one month apart. The combined analysis from both dosing regimens (n=11,636) resulted in an average efficacy of 70%. All results were statistically significant ($p<=0.0001$). More data will continue to accumulate and additional analysis will be conducted, refining the efficacy reading and establishing the duration of protection.

An independent Data Safety Monitoring Board determined that the analysis met its primary endpoint showing protection from COVID-19 occurring 14 days or more after receiving two doses of the vaccine. No serious safety events related to the vaccine have been confirmed. AZD1222 was well tolerated across both dosing regimens.

AstraZeneca will now immediately prepare regulatory submission of the data to authorities around the world that have a framework in place for conditional or early approval. The Company will seek an Emergency Use Listing from the World Health Organization for an accelerated pathway to vaccine availability in low-income countries. In parallel, the full analysis of the interim results is being submitted for publication in a peer-reviewed journal.

The pooled analysis included data from the COV002 Phase II/III trial in the UK and COV003 Phase III trial in Brazil. Over 23,000 participants are being assessed following two doses of either a half-dose/full-dose regimen or a regimen of two full doses of AZD1222 or a comparator, meningococcal conjugate vaccine called MenACWY or saline. The global trials are evaluating participants aged 18 years or over from diverse racial and geographic groups who are healthy or have stable underlying medical conditions.

Clinical trials are also being conducted in the US, Japan, Russia, South Africa, Kenya and Latin America with planned trials in other European and Asian countries. In total, the Company expects to enrol up to 60,000 participants globally.

The Company is 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.