From: [redacted]
[redacted] BRETON Thierry (CAB-BRETON)
Cc: [redacted]; CAB BRETON CONTACT
Subject: AZD1222 US Phase III trial met primary efficacy endpoint in preventing COVID-19 at interim analysis
Date: lundi 22 mars 2021 08:03:15
Attachments: AZD1222_PhIII US HLR_RNS.pdf

Dear Commissioner Breton,

I am pleased to inform you that today AstraZeneca announced positive high-level results from an interim analysis of the AstraZeneca US Phase III trials of AZD1222.

The data show that the vaccine demonstrated statistically significant **vaccine efficacy of 79% at preventing symptomatic COVID-19** and **100% efficacy at preventing severe disease and hospitalisation.** In particular:

- Vaccine efficacy was **consistent across ethnicity and age**. Notably, vaccine efficacy was **80% in participants aged 65 years and over**, who represented approximately 20% of participants.
- This interim safety and efficacy analysis was based on 32,449 participants across 88 trial centres in the US, Peru and Chile. The vaccine was **well tolerated**, and the data safety monitoring board (DSMB) identified **no safety concerns** related to the vaccine.
- During the interim analysis, the DSMB also conducted a **specific review of thromboembolic events** across the US trial data. The DSMB found **no increased risk of thrombosis or events characterised by thrombosis** among the 21,583 participants receiving at least one dose of the vaccine. The specific search for cerebral venous sinus thrombosis (CVST) found no events in this trial.

These results add to the growing body of evidence that shows this vaccine is well tolerated and highly effective against COVID-19 across all adult age groups. We look forward to continued cooperation with you and your team to further strengthen our capacity for COVID-19 vaccine production and pandemic preparedness in Europe, including through collaboration with your Task Force for Industrial Scale-up of COVID-19 vaccines and the future European Health Emergency Preparedness and Response Authority (HERA).

Please find attached the official company announcement with further information. I remain at your disposal should you wish to discuss any aspects of today's announcement or related matters with you and your team in more detail.

Best regards,

[redacted]