One of the studies, 330 subjects vaccinated and T. November 15, 2020.

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members and their expertise and are fully equipped to provide the necessary advice. The Board of Directors regrets the resignation of Mrs. G. C. N. D. and the resulting inability of the Group to maintain its current level of commercial activity,

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As a result, the Board of Directors has decided to elect Mrs. G. C. N. D. as a member of the Board of Directors and to remove Mr. G. D. from its membership. The Board of Directors wishes to thank Mr. G. D. for his contribution to the Group’s

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AZD1222 Induced Robust Antibody Responses At Levels In A Similar Range To Those Seen In Convalescent COVID-19 Patients In Phase I/II Study COV001

Neutralizing activity against SARS-CoV-2 virus is boosted after a second dose in older adults

AZD1222 Induced A Robust Th1 Biased T-Cell Response In COV001 And COV002 Participants

US Phase III Trial D8110C00001 Design, Objectives, Diversity

Phase III Study D8110C00001 To Evaluate Safety And Efficacy Of AZD1222 In Over 30,000 Volunteers

Phase III Study D8110C00001 Diversity And Enrollment

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AZD1222 Storage And Administration

**Storage**
- Refrigerator
  - Store in refrigerator (2 to 8°C)
  - Shelf life = 6 months
  - Do not freeze
  - Keep vials in outer carton to protect from light

**Administration**
- Multi-dose Vial
  - After first puncture cumulatively store up to 6 hours at room temperature or up to 48 hours at 2-8°C with total storage time not to exceed 48 hours.
  - No dilution or reconstitution

Summary: AZD1222 offers a potential to address the Global COVID-19 Crisis

- AZD1222 induces robust immune responses against the SARS-CoV-2 S protein:
  - Spike Antibodies increased after a second dose with GMTs comparable to convalescent sera
  - Neutralizing Antibodies titers observed in all participants following 2nd dose
  - Strong Th-1 biased CD4+ T Cell response observed
- US Phase III study ongoing with 32,459 participants enrolled with co-morbidities, older adults and diverse backgrounds
  - 26,327 received second dose by Jan 21, 2021
  - Efficacy and safety were demonstrated in four Phase I-III studies in UK, Brazil and South Africa
  - AZD1222 has the potential to address the SARS-CoV-2 pandemic and has been authorized in 18 countries (under emergency use or full approval as of January 25, 2021)

Thank You
to our collaborators, investigators and subjects:
- University of Oxford
- BARDA
- NIAID
- DoD
- The AstraZeneca Team
- Clinical trial sites personnel and investigators
- All our trial participants

Thank You to our collaborators, investigators and subjects:
### Phase III Study D8110C00001 Clinical Hold Summary

- Study was initiated on 28 Aug and paused by AstraZeneca on 6 Sep. Clinical hold was issued on 9 Sep and lifted on 23 Oct; study restarted on 28 Oct.
- The study was paused due to an event of transverse myelitis reported in the Phase II/III study conducted by the University of Oxford in the UK.
- Information provided to FDA:
  - Additional details on neurological events in studies sponsored by AstraZeneca and University of Oxford.
  - Analyses of available clinical safety data from AZD1222 and ChAdOx1 viral vector platform studies.
- Changes in study conduct implemented:
  - Updated risk language in Informed Consent Form (ICF) and Investigator Brochure (IB).
  - Protocol changes.
  - Establishment of independent expert neurology panel.
  - Accelerated/increased safety reporting.

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### Phase III Study D8110C00001 Case Definition Of Symptomatic COVID-19 Disease

**Primary efficacy endpoint:** Symptomatic illness
- First case of SARS-CoV-2 RT-PCR positive symptomatic illness occurring > 14 days post administration of study intervention. Participants included if they meet following criteria at any point from Day 1 (initial visit) through Day 14.

**Safety endpoint:** Occurrence of adverse events:
1. Incidence of AEs for 28 days post each dose.
2. Incidence of AEs, MAEs, and AESIs from Day 1 post treatment throughout study.

#### Symptoms

<table>
<thead>
<tr>
<th>Specificity (Pathogen Confirmation)</th>
<th>Category A: Lower respiratory tract involvement (one or more)</th>
<th>Category B: Systemic/other symptoms (two or more)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 confirmed</td>
<td>* Pneumonia diagnosed by chest x-ray or CT scan</td>
<td>* Fever &gt; 37.8˚C (100˚ F) or feverishness</td>
</tr>
<tr>
<td><strong>Primary efficacy endpoint:</strong></td>
<td>* ILD, O2 sat of ≤ 94% on room air or 2 percentage point drop from baseline</td>
<td>* New or worsening cough</td>
</tr>
<tr>
<td><strong>Safety endpoint:</strong></td>
<td>* New or worsening dyspnea/shortness of breath</td>
<td>* Myalgia/ muscle pain</td>
</tr>
<tr>
<td></td>
<td>* New or worsening cough</td>
<td>* Fatigue that interferes with activities of daily living</td>
</tr>
<tr>
<td></td>
<td>* New or worsening cough, cyanosis, or mental status changes</td>
<td>* Vomiting or diarrhea</td>
</tr>
<tr>
<td></td>
<td>* New or worsening cough, cyanosis, or mental status changes</td>
<td>* Seizures or agitation</td>
</tr>
</tbody>
</table>

AE = adverse event; AESI = adverse event of special interest; MAAE = medically attended adverse events.