Data package supporting bamlanivimab 700 mg* for the treatment of patients with mild to moderate Covid-19 at high risk for severe disease and/or hospitalisation :

- **Clinical efficacy and safety**: data supporting the above indication and the US EUA were published in the New England Journal of Medicine [add link]. The data package will comprise a clinical overview, including a full benefit/risk assessment and dose justification supported by a population pharmacokinetics/pharmacodynamics report. There is no clinical study report available since the study is ongoing. A clinical study report is not expected until 2021.

  [*] a single intravenous (IV) infusion of 700 mg administered as soon as possible after positive viral test for SARS-CoV2 and within 10 days of symptom onset.

  Key clinical elements are:
  - *COVID-19 is a life-threatening and serious debilitating condition*
  - *High unmet need: no treatments approved for mild to moderate COVID-19 patients who are at high risk of progressing to severe COVID-19 illness and/or hospitalisation*
  - *Bamlanivimab benefits when administered in early disease*
    - *Reduction in viral load*
    - *Reduction in hospitalisations and emergency room visits associated with COVID-19 illness*
    - *Reduced symptoms of COVID-19 illness*
  - *Potential risks*
    - *Anticipated risk considered low based on mechanism of action*
    - *Potential for hypersensitivity, infusion-related reactions, and theoretical risks of antiviral resistance and immune response attenuation*
  - *Positive benefit/risk*
- **Nonclinical safety**: The data package will comprise a **nonclinical overview** and **study reports** for all the completed nonclinical studies.
- **Quality**: **quality overall summary and Quality Dossier.** Note this is equivalent to what would be provided in the context of a clinical trial application as opposed to a marketing authorisation application
- **Label**: **English language**-only carton labelling and vial labelling. The package insert will not be included in the carton. It will be available via QR code that takes the patient and HCP to a landing page, where they can download the instructions for use in their local language. Due to supply constraints, this is the only way in which the product will be labelled.

The package described above represent the full extent of the available data to support the proposed indication, and the pharmaceutical quality of the product available for supply. There are no further trials investigating the use of bamlanivimab as monotherapy in this patient population. As such, the items above constitute the data package for temporary or emergency use.