From: [redacted] (SANTE)
To: BUCHER Anne (SANTE); ROSSIDES Giorgos (CAB-KYRIAKIDES); OJALA Annukka (CAB-KYRIAKIDES); NEOCLEOUS Olympia (CAB-KYRIAKIDES); PRAINSACK Ines (CAB-KYRIAKIDES); SEYCHELL Martin (SANTE); RYS Andrzej Jan (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); BUXHOEVEDEN Daphne (SANTE); VAN CANGH Thomas (SANTE); CARROUEE Lucie (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Cc: MUELLER Anne (CAB-KYRIAKIDES); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Subject: Gilead Sciences - meeting report 2 June 2020
Date: mercredi 3 juin 2020 18:49:47

BTO – 2 June 2020 Video-call – Commissioner Kyriakides and Gilead Sciences Europe Ltd

Present: Commissioner Stella Kyriakides; Cabinet Members: Giorgos Rossides (Head of CAB), Annukka Ojala (Dep Head of CAB), Olympia Neocleous, Ines Prainsack, Chrystalla Papanastasiou, Anne Mueller

DG SANTE: Martin Seychell (DDGI), Andrzej Rys (Dir B) [redacted]

Gilead Sciences: [redacted]

European Medicines Agency: [redacted]

This was a follow-up to the meetings on 7 May & 7 April 2020.

Summary - Gilead gave an update on recently available data on the investigational medicine remdesivir. They intend to submit an application for a conditional marketing authorisation for assessment by the European Medicines Agency at the end of the week (5 June). For supply there are still only 1.5 million vials for donation worldwide, there needs to be agreement of US government for export of US production. Supply will increase in the autumn and will include production outside the United States. Gilead is interested in exploring the possibility of using the Joint Procurement mechanism as a means to distribute the potential supply for the EU according to the medical needs of the Member States. The Commissioner stressed the importance of distribution on a needs basis first.

Details of the discussion

Gilead representatives explained the **emerging evidence**, noting that more details of the US National Institute of Allergy and Infectious Diseases (NIAID) study had been published. The median recovery time with 10 day treatment was 11 days compared to of 15 days in the placebo group. In Gilead's trial comparing 5 day and 10 day treatment, in severe COVID-19 patients the clinical improvement was similar. Gilead had issued a press release[1] on 1 June with the results of the SIMPLE trial with evidence of improvement in time to recovery in COVID-19 patient with moderate pneumonia, this was significant

compared to the standard of care in the 5 day remdesivir treatment group although significance was not reached in the 10 day treatment group. Gilead will submit this data to the European Medicines Agency (EMA) to support the treatment indication they will be seeking. Gilead intend to submit to EMA on 5 June an application for a conditional marketing authorisation supported by a dossier with all the currently available evidence.

The **Commissioner** asked for clarification on the expected **supply** in the EU. **Gilead** explained that the supply would continue to be limited until the end of the year by when additional manufacturing capacity would be on stream. At the moment, they are supplying through clinical trials, named patient or compassionate use programmes, or emergency/temporary authorisations. The limited supply means that Gilead has to have permission from the US government to ship the product to other countries. The 6 month lead-time to produce the active ingredient means that the additional manufacturing capacity will not be on stream until around October (expect additional 4 million vials) and by the end of the year another 4 million vials. Some of this additional manufacturing is outside the USA.

Gilead explained they are interested in the possibility of the supply of remdesivir to be initially through a **joint procurement** process as they believe it would allow faster access on the basis of need and would like to have all Member States supplied through this mechanism with the Commission determining the allocation. They wish to seek a mechanism for distribution on the basis of medical need and to avoid stockpiling during the period while stocks are limited. They wish to avoid having parallel discussion with Member States for the supply during the initial period, but the supply after the first 6 months would be through the usual process of pricing and reimbursement procedures with individual Member States. **Martin Seychell** noted that the Joint Procurement is a voluntary process and asked how limited the supply would be to the EU. Gilead was unable to say what the supply to the EU would be.

The **Commissioner** stressed the importance of having distribution on a needs basis first.

END

Author: [redacted]

---

[1] https://www.gilead.com/news-and-press/press-room/press-releases/2020/6/gilead-announces-results-from-phase-3-trial-of-remdesivir-in-patients-with-moderate-covid-19