

From: [REDACTED] (SANTE)
Sent: mercredi 8 avril 2020 13:10
To: [REDACTED] (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE); [REDACTED] (SANTE)
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE);
[REDACTED] (SANTE); SANTE CONSULT-B5
Subject: BTO report - video call with Gilead Sciences - 7/4/2020

Dear all,

With thanks to [REDACTED] please find below a summary from the video-call with Gilead Sciences.

Kind regards

Tuesday 7 April 2020

Video-call- Gilead development efforts on the potential treatment for COVID-19

Gilead: [REDACTED], Gilead Sciences [REDACTED]
[REDACTED] Gilead Sciences [REDACTED]

EC: The Commissioner Stella Kyriakides and the Cabinet Members: Olympia Neocleous, Giorgos Rossides, Anne Mueller, Ines Prainsack, Annukka Ojala
[REDACTED] (DG SANTE/B5)

EMA : Guido Rasi, [REDACTED],

Gilead firstly presented the Company's efforts to address COVID-19 crisis. Gilead highlighted its policy of humanitarian efforts in current times. Remdesivir, it's pipeline product, lacks the marketing authorisation, and its efficacy and safety profile have not been demonstrated. It is, however, their intention to apply for full marketing authorisation.

COVID-19 experience comes mainly from the compassionate used schemes, so far, but the feedback from the field is difficult to interpret. Company also indicated the aims to increase production capacity in order to fulfil the demand.

The Commissioner asked about clinical trials and company's priorities with deliveries and highlighted actions taken in the EU to address the increased demand on the medicines and medical devises during crisis.

Gilead explained that the clinical trials (CT) scheme is on going. They highlighted that the importance to supply clinical trials is recognised, in compassionate use schemes they try to fulfil MS needs.

Gilead is involved in the solidarity and discovery CT networks.

EMA explained that there are tools for accelerated assessment and authorisation pathways. CTs are priority, with the controlled setting, and supplies for CT should be guaranteed.

In the end the **Commissioner** thanked the company for the information and indicated COM willingness to follow the evolution of the field, and suggested the next TC for the last week of April 2020.

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Out of scope

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