EN E-006511/2020 Answer given by Ms Kyriakides on behalf of the European Commission (17.2.2021)

The Commission was not informed about the interim results of the World Health Organization Solidarity Trial during the negotiations with Gilead.

The European Medicines Agency (EMA) has requested access¹ to the data from the Solidarity Trial. Once the data are available, EMA will assess the evidence, together with other relevant data, to see if any changes are needed to the marketing authorisation of Veklury (remdesivir) in the EU.

The Commission does not plan to renegotiate the contract, as remdesivir continues to have a conditional marketing authorisation². The maximum amount in the framework contract³ is determined by the needs identified during the procedure by the EU Member States and other countries⁴ participating in this joint procurement.

¹ https://www.ema.europa.eu/en/news/update-remdesivir-ema-will-evaluate-new-data-solidarity-trial

² https://ec.europa.eu/health/documents/community-register/html/h1459.htm

³ https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/public-

health en#ensuringtheavailabilityofsuppliesandequipment

⁴ https://ec.europa.eu/health/preparedness response/joint procurement/jpa signature en#