

Mr Marcelo Palacios President of the Scientific Committee of SIBI 3, Humendal Square 33205 Gijón SPAIN

16 December 2020 EMA/689727/2020 European Medicines Agency

Dear Ms Palacios,

Subject: Your letter dated 26 November

I am responding to your query regarding the use of antivirals as preventative treatment for COVID-19.

We fully agree that there is an urgent need to end the pandemic and we would like to reassure you that EMA and the EU Network are doing everything it can to support developers in generating the robust clinical data that is needed to show that medicines (including both vaccine and therapeutics) are safe and effective for the treatment and prevention of COVID-19.

Please note that EMA has not received any applications for marketing authorisation for antivirals as sprays, inhalers, atomizers, gradual release pills of drugs, or creams, solutions to be used in the prevention of COVID-19. In order for EMA to assess such use, we need to receive an application from the pharmaceutical company who has developed the medicine, providing us with the evidence they hold of its safety, quality and effectiveness.

Although EMA is not able to directly fund scientific research, it can, upon request from a company developing a medicine, provide guidance and direction on the best methods and study designs to generate robust information on how well a medicine works and how safe it is.

In closing this letter, let me stress again the commitment of EMA and its staff to continue doing all we can within our mandate to contribute to global efforts to drive this pandemic to an end. In particular we will ensure that we evaluate promptly all applications of medicines and vaccines for treating and preventing COVID-19.

With best wishes,

Emer Cooke

Executive Director

