From: [redacted] <[redacted]@incisivehealth.com>
Sent: mardi 8 juin 2021 13:49
To: [redacted](SANTE)
Cc: SANTE CONSULT-C1; . [redacted]; [redacted]
Subject: Re: COVID-19 therapeutics strategy - request for further information

Dear [redacted]

Thank you very much for your response.

We understand from your email that we should get in touch with the EMA directly considering the Commission is looking to select a shortlist of promising treatments by the end of the month.

Could you also kindly clarify whether the Commission is only looking to fund treatments that are close to filing marketing authorisation or will promising treatments in Phase I/II also be considered for the shortlist?

We look forward to hearing from you.

Best wishes

[redacted]

From: [redacted] <[redacted]@ec.europa.eu> on behalf of [redacted] <[redacted]@ec.europa.eu>
Date: Friday, 4 June 2021 at 16:25
To: [redacted] <[redacted]@incisivehealth.com>
Cc: "SANTE-CONSULT-C1@ec.europa.eu" <SANTE-CONSULT-C1@ec.europa.eu>, [redacted] <[redacted]@ec.europa.eu>
Subject: FW: COVID-19 therapeutics strategy - request for further information

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Dear [redacted],

Thank you for your interest in the EU strategy for Covid-19 therapeutics as showed in your emails addressed to Pierre Delsaux (Deputy Director-General - for Health) and John F. Ryan (Director Public Health).

The aim of this strategy is to put in place a mechanism to speed up the entire process of development of therapeutics (encompassing clinical research and clinical trials, the manufacturing, the purchase and the availability of the products in the EU).

The majority of the actions foreseen in the strategy are at an early stage of development and they will be defined more in detail in the near future.

Concerning your question on how a portfolio of 10 potential COVID-19 therapeutics will be drawn up, the exact process for the inclusion in the list still needs to be finalised. For your information, the European Medicines Agency (EMA) is currently following-up a number of COVID-19 therapeutics under development. The ones at the more advanced stage of development have been included in the process to accelerate the scientific assessment through rolling review.

In a rolling review, EMA's Committee for Medicinal Products for Human Use (CHMP) reviews data as they become available from ongoing studies, before a formal application for a marketing authorisation is submitted. Once the CHMP decides that sufficient data are available, the formal application can be submitted by the company. By reviewing the data as they become available, the CHMP can give sooner its opinion on whether the medicine or vaccine can be authorised. If the benefit risk of the medicines is considered favourable, the EMA will recommend to the European Commission to grant a marketing authorisation.

For more information you may check the EMA page on COVID-19 therapeutics: Treatments and vaccines for COVID-19 | European Medicines Agency (europa.eu) or the specific page for scientific advice for developers of a potential COVID-19 therapy: Scientific advice and protocol assistance | European Medicines Agency (europa.eu)

It is also possible for companies to submit applications whether or not they have received scientific advice. Once the development and the associated evidence is considered sufficient to support a marketing authorisation the dossier can be submitted for assessment by the EMA, details of how this can be done are also available on the EMA website: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/guidance-developers-companies/covid-19-guidance-evaluation-marketing-authorisation. .

The Commission hopes that the support for the development of COVID-19 medicines will help bring safe and effective treatments earlier to patients, which will be important in the ongoing actions against the pandemic.

Hope this clarifies,

Kind regards

[redacted]

European Commission
DG SANTE
[redacted] Unit C1 'Health promotion, disease prevention, financial instruments'

From: [redacted] <[redacted]@incisivehealth.com>
Sent: Monday, May 31, 2021 5:14 PM
To: DELSAUX Pierre (SANTE) <[redacted]@ec.europa.eu>
Cc: Subject: COVID-19 therapeutics strategy - request for further information

Dear Mr Delsaux

We are contacting you on behalf of AlloVir, a clinical stage biopharmaceutical company developing novel Virus Specific T-cell therapies to treat or prevent life-threatening viral infections in high-risk patients. We are reaching out to you in the context of the Commission's recent COVID-19 therapeutics strategy announcement. AlloVir has a T-cell therapy for the treatment of High-Risk Patients with COVID-19 that received FDA clearance to start clinical trials in September 2020.

We have understood from Mr John Ryan's intervention in the European Parliament's ENVI Committee on 26 May, that the Commission will be reviewing candidate therapeutics and shortlisting ten by the end of June. AlloVir would be interested in understanding what the formal process to enter this is and how AlloVir should approach the Commission and the EMA.

We look forward to your response and please feel free to contact us should you have any questions.

Best wishes

[redacted]

[redacted]

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make it matter.

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