

From: [REDACTED] (SANTE)
Sent: mercredi 9 juin 2021 15:57
To: [REDACTED] (SANTE)
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: FW: European Commission's COVID-19 therapeutics strategy

To be registered in ARES.. I will update excel file
[REDACTED]

From: [REDACTED] <[REDACTED]@hkstrategies.com>
Sent: Wednesday, June 9, 2021 3:52 PM
To: SANTE CONSULT-C1 <SANTE-CONSULT-C1@ec.europa.eu>
Cc: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>
Subject: RE: European Commission's COVID-19 therapeutics strategy

Dear Sir/Madam,

Thank you very much for your reply. The information provided has been more than useful and is greatly appreciated.

If you will allow me, I have two follow-up questions:

- As you mention, the aim of this strategy is to speed up the entire process of the development of therapeutics. What specific role will the innovation booster play in this process? Will it remain operational after the initial selection phase (which aims to deliver 5 new and approved therapeutics by the end of the year)?
- The strategy mentions different initiatives in charge of mapping and selecting promising therapeutics. Will scientific review by EMA remain the initial step for developers of promising therapeutics? Or will the therapeutics strategy foresee different routes for mapping and selecting?

Our client is developing a potentially interesting COVID-19 therapy and is wondering how it can engage with this new strategy in order to facilitate this innovation.

Thanks again and looking forward to your reply.

With high regards,

[REDACTED]

[REDACTED]

[REDACTED]@hkstrategies.com
D: +32 [REDACTED]

M: +32 [REDACTED]

From: SANTE-CONSULT-C1@ec.europa.eu <SANTE-CONSULT-C1@ec.europa.eu>
Sent: Friday, 4 June 2021 16:09
To: [REDACTED] <[REDACTED]@hkstrategies.com>
Cc: SANTE-CONSULT-C1@ec.europa.eu; [REDACTED];
[REDACTED] <[REDACTED]@ec.europa.eu>
Subject: FW: European Commission's COVID-19 therapeutics strategy

Dear [REDACTED],

Your message of 24 May to [REDACTED] was forwarded to this unit for reply.

Thank you for your interest in the EU strategy for Covid-19 therapeutics.

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 planned in the strategy are now at an early stage of implementation and they will be defined more in detail in the near future.

Concerning the specific question on the selection criteria for scanning/mapping candidate therapeutics, the exact process of identifying them still needs to be finalised.

However, for your information, concerning the portfolio of 10 potential COVID-19 therapeutics that will be drawn up, the European Medicines Agency (EMA) is currently following-up a number of COVID-19 therapeutics under development including small molecules and monoclonal antibodies, antivirals and immunomodulators. 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 reach its opinion sooner on whether or not 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 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.

Kind regards

SANTE Unit C1

From: [REDACTED] <[REDACTED]@hkstrategies.com>
Sent: Monday, May 24, 2021 11:19 AM
To: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>
Subject: European Commission's COVID-19 therapeutics strategy

Dear [REDACTED],

I hope all is well.

I am contacting you in name of one of our clients, regarding the [European Commission's COVID-19 therapeutics strategy](#).

We have a couple of questions on this, seeing as we were not able to find any additional information regarding certain procedures. We were wondering if you could provide us with some more information on the following:

- What are the selection criteria for scanning/mapping candidate therapeutics? Are there ways of applying or making oneself known for this procedure?
- The current timeline notes the selection of 5 promising candidate therapeutics by June. Are these specific potential therapies or categories of therapeutics (anti-body treatment, anticoagulation drugs, etc.)?
- If there are ways for potentially promising therapeutics to make themselves known to the European Commission, through what mechanism/procedure should this happen?

Do let us know if you require any additional information. We look forward to your response.

With high regards,

[REDACTED]

[REDACTED]

[REDACTED] [@hkstrategies.com](mailto:[REDACTED]@hkstrategies.com)

D: +32 [REDACTED]

M: +32 [REDACTED]