From: SANTE CONSULT-C1
Sent: lundi 21 juin 2021 15:35

To:

Cc: (SANTE); SANTE CONSULT-C1

Subject: RE: European Commission's COVID-19 therapeutics strategy

Dear

Thank you for your follow-up email.

Concerning your first question on the Therapeutics Innovation Booster: the aim is to identify potentially promising therapies for the treatment of patients COVID 19 (including therapeutics for out-patient treatment in the community once the presence of infection has been confirmed). The Therapeutics Innovation Booster will specially focus on candidates that are at early stages of the R&D pipeline and that will need assistance before getting to the market. The booster is intended to remain in place after the present COVID-19 emergency for future such events and therefore it is expected to remain operational after the initial selection phase.

<u>Concerning your second question</u>, as mentioned in my previous reply, the exact process of identifying them is being finalised.

I take advantage of this email to inform you that following the adoption of the EU Strategy for COVID19 Therapeutics, the European Commission is organising an **EU matchmaking event on COVID19 therapeutics on the 12**th **and 13**th **of July 2021**. The participation in the matchmaking event on 12-13 July will be open to a range of organisations and we encourage you to participate at this event. Please find some more detailed information on the matchmaking event below.

Thanks again, best regards,

SANTE UNIT C1



European Commission

Directorate—General for Health and Food Safety
Unit C1 Health promotion, disease prevention, financial instruments

EU matchmaking event on COVID19 therapeutics on the 12th and 13th of July 2021

Following the adoption of the EU Strategy for COVID19 Therapeutics (<u>EU Therapeutics Strategy (europa.eu</u>)), the European Commission's Task Force for Industrial Scale-Up of COVID19 Vaccines and Therapeutics is organising an **EU matchmaking event** on **COVID19 therapeutics on the 12th and 13th of July 2021**. The objectives are to support the acceleration of the development and upscale of Covid-19 therapeutics production, enhance the participation of EU companies in the Covid-19 therapeutics value chains, speed up connection between organisations and help in retro-planning strategy for production.

A preparatory webinar took place on the 14th of June 2021. If you could not join us, please note that the webinar was recorded and uploaded, together with all information that you need to participate, in the matchmaking platform here: European Matchmaking event - Development and production of COVID-19 therapeutics - Info (b2match.io)

Please note that the registration began on 14 June 2021 at 2.30pm CEST.

We would also like to invite you to join the **technical webinar** that will take place on the 30th of June 2021. This webinar will provide more technical information on how to book meetings. The link to the webinar is here https://zoom.us/i/96622900660?pwd=TEdxdmlxd05tZENSaHM2WFFyczhxZz09

We would also like to inform you that the Task Force has launched an **EU Survey** with the purpose of gaining understanding on the **needs of the EU organisations working in the development of new and repurposed medicines for COVID-19 therapeutics,** i.e. medicines specifically developed for an indication in treatment of COVID-19. We encourage you to participate in this EU Survey by the 25th of June 2021. Your answers will help us shape EU support in the best possible way. Please be aware that we intend to gather the maximum of answers as soon as possible in view of the urgency of the subject. The link to the EU Survey is here: https://ec.europa.eu/eusurvey/runner/1ebcfe3c-498f-f080-e383-9a55fc44f00e
For any questions, please don't hesitate to contact us at: GROW-TFIS@ec.europa.eu

Fro	m:	<	@hkstrate	egies.com>					
Sent: Wednesday, June 9, 2021 3:52 PM									
To: SANTE CONSULT-C1 <sante-consult-c1@ec.europa.eu></sante-consult-c1@ec.europa.eu>									
Cc:	(SANTE) <	<u>a</u>	ec.europa.eu>;		(SANTE)			
<	<u>.</u>	@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,



D: +32

M: +32

From: SANTE-CONSULT-C1@ec.europa.eu <SANTE-CONSULT-C1@ec.europa.eu>

Sent: Friday, 4 June 2021 16:09

To: < @hkstrategies.com>

Cc: SANTE-CONSULT-C1@ec.europa.eu; < @ec.europa.eu>;

@ec.europa.eu>

Subject: FW: European Commission's COVID-19 therapeutics strategy

Dear ,

Your message of 24 May to 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: <u>Treatments and vaccines for COVID-19 | European Medicines Agency (europa.eu)</u> or the specific page for scientific advice developers of a potential COVID-19 therapy: <u>Scientific advice and protocol assistance | European Medicines Agency (europa.eu)</u>

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:	<	@hkstrategies.com>

Sent: Monday, May 24, 2021 11:19 AM

To: (SANTE) < @ec.europa.eu>
Subject: European Commission's COVID-19 therapeutics strategy

Dear

I hope all is well.

I am contacting you in name of one of our clients, regarding the <u>European Commission's</u> <u>COVID-19 therapeutics strategy</u>.

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,

@hkstrategies.com

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