From: [redacted] (SANTE)
Sent: vendredi 4 juin 2021 18:34
To: [redacted] (SANTE)
Cc: [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)
Subject: FW: Ares - Document "RE: EU Strategy on Therapeutics - Clarification" - Ares(2021)3608077

Categories: Red Category

Dear [redacted] could you pls file it in Ares and elsewhere needed.
Thanks, best, [redacted]

From: [redacted] (SANTE)
Sent: Friday, June 4, 2021 6:32 PM
To: [redacted]
Cc: [redacted]
Subject: FW: Ares - Document "RE: EU Strategy on Therapeutics - Clarification" - Ares(2021)3608077

Dear [redacted],

Thank you for your interest in, and support for, the EU COVID-19 therapeutics strategy as expressed in your email below of 1 June 2021.

The aim of the therapeutics strategy is to put in place a mechanism to speed up all the process, the development of products, the clinical research and clinical trials, the manufacturing, the purchase and the availability of the COVID-19 therapeutic medicines in the EU.
With respect to the authorisation of medicines in the EU, for centrally authorised medicines the European Medicines Agency (EMA) has engaged with developers of potential COVID-19 therapeutics. The aim is to provide advice on regulatory requirements so that any promising medicines can be made available as quickly as possible to patients, initially in the clinical trial setting and then, once authorised, through its placement on the market.

If developers of a potential COVID-19 therapy would be interested in seeking scientific advice from the EMA, details on how to do so are available on the EMA website: https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance.
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.

With best regards,

[redacted]

European Commission
Directorate-General for Health and Food Safety
Unit C1 Health promotion, disease prevention, financial instruments

From: [redacted]
Sent: Tuesday, June 1, 2021 7:23 AM
To: [redacted] (SANTE) < [redacted] @ec.europa.eu>
Cc: [redacted]
Subject: EU Treatment Strategy - meeting request UNION therapeutics

Dear [redacted],

I am writing to you from Lykke Advice on behalf of our client **UNION therapeutics**, a clinical stage pharmaceutical company specialised in the research and development of medicinal products with microbiological and immunological effects. We attended the webinar on the 20th of May, where the treatment strategy was presented. We are taking the liberty to contact you as you suggested during the webinar to see if we could have a meeting in the coming weeks to discuss further the strategy and understand if UNION therapeutics can become one of the 10 therapies selected in June.

UNION has been working in Brussels to **drag the policymakers and other stakeholders' attention to the need of prophylaxis and treatment therapeutics to complement the COVID-19 response**. In fact, UNION strongly believes that therapeutics can play a crucial role in where vaccines risks being less effective e.g., in the protection of vulnerable groups (such as patients with immunosuppression) or against emerging variants of concern that may prove resistant to existing vaccines. In this perspective, UNION is developing two therapeutics based on niclosamide salt solutions, which recently demonstrated potential to eradicate Sars-CoV-2 in vivo murine models, with potency 30 times higher than remdesivir: a nasal spray aimed to COVID-19 prevention in vulnerable groups with risks of severe complications if infected by SARS-CoV-2 and for post-exposure, early-treatment prophylaxis i.e., in between infection and manifestation of symptoms; and a nebulisation for the treatment of inpatients to prevent sever complications of COVID-19 and reduce their hospitalisation time.

For the production of both products, **UNION has already identified key partners for a fully EU-based supply chain.**

In view of this, I attach a position paper outlining the general position of UNION, but we would like to meet and understand more in details about the criteria the EU will select the 10 therapies. Would you be available for a meeting with UNION therapeutics in the coming days to discuss the actions of the Strategy and the criteria more in details?

Kind regards,

[redacted]
[redacted]
Mobile: +32 [redacted]
Twitter: [redacted]
[redacted]
Transparency Register: [redacted]