Questions and Answers: COVID-19 Therapeutics Strategy – list of 5 candidate therapeutics

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Why do we need a list of the five most promising COVID-19 therapeutics?

While the COVID-19 vaccination campaign progresses well in Europe, the availability of therapeutics for affected patients is still limited, with so far one product, remdesivir, authorised at EU-level. On 6 May 2021, the European Commission published the EU Strategy on COVID-19 therapeutics, which addresses therapeutics research, development, authorisation, manufacturing and deployment.

The EU COVID-19 Therapeutics Strategy maps out a number of actions to identify candidate therapeutics. The Commission has committed under the strategy to establish a list of five promising candidates by June 2021. A broader portfolio of ten potential candidates will follow by October 2021. An interactive mapping platform for promising therapeutics will be set up under the Health emergency preparedness and response authority (HERA) by mid-2022. The Commission is also preparing a COVID-19 'therapeutics innovation booster platform' to take stock and develop a clear overview of the COVID-19 therapeutics projects under earlier stages of development in order to better support development of potential therapeutics.

What are the criteria for selecting the first five therapeutics?

The list is based on objective criteria, namely the rolling review evaluation by the European Medicines Agency (EMA). A rolling review is a regulatory tool that EMA uses to speed up the assessment of a promising medicinal products during a public health emergency. EMA includes products in the rolling review procedure based on promising preliminary results from clinical studies. There are currently five front-runner COVID-19 treatments under evaluation by EMA. These products are in an advanced stage of development and have a high potential to be among the new COVID-19 therapeutics to receive authorisation.

How will you get from the list of five to a broader portfolio (list of ten)?

The initial list of five therapeutics is a snapshot of the most advanced COVID-19 therapeutics in terms of development. These therapeutics are already under evaluation by EMA, and they can theoretically be approved by the end of the year, if clinical data confirm that they are safe and efficacious.

The Commission is also working on a framework for a broader and diverse portfolio of therapeutics with the help of the HERA expert group on variants. Initially it will be a list of at least 10 therapeutics and evolve into a continuous mapping of therapeutics development. The portfolio will indicate products in the research and development pipeline which have the potential to serve as the EU's future therapeutic arsenal to fight the disease, and should remain live and dynamic given the emerging and circulating variants.

As opposed to the list of five, which only takes into account the rolling review process, the broader portfolio will be based on more criteria to be defined by the expert group. The selection process will be objective and science based and the selection criteria will be also agreed with the Member States.

Since different types of products are needed for different patient populations and different stages and severity of the disease, the expert group will identify product categories and select the most promising therapeutics candidates for each category. Rather than a list only, the diverse portfolio will provide a mapping of the most advanced candidates in the different categories, evolving as candidates progress or fail. The portfolio could be used also as the basis for other activities in the strategy, such as the Innovation Booster, HERA, EU-FAB, match-making events, joint procurement, advance purchase agreements, innovation partnership and rescEU stockpiling.

What will be the benefit of including a product on the list of therapeutics?

For the moment, there are no specific financial instruments attached to the portfolio, however the relevant candidates will benefit from regulatory flexibility as set out in the Therapeutics Strategy,

while making sure medicinal products are safe and efficacious. Examples of flexibility are rolling reviews, conditional marketing authorisations, or flexible labelling and packaging requirements. They can also benefit from scientific support by EMA or by the match making activities under the EU therapeutics strategy.

Nevertheless, the portfolio approach will support the strategy's ambition to authorise three new therapeutics by October 2021, and possibly two more by the end of the year. It will also facilitate the identification of suitable candidates for joint procurement.

What if a product has not been included in the list of five?

The Commission is working on a broader and diverse portfolio of therapeutics. The portfolio will cover different types of products needed for different patient populations and different stages and severity of the disease. It will identify the types of products that are in the pipeline and the products that are still needed, as well as the gaps in treatment options.

When will the five therapeutics on the list be authorised?

Given that these products are in an advanced stage of development (under the rolling review process) they have a high potential to be among the three new COVID-19 therapeutics to receive an authorisation (by October 2021), provided the final data demonstrate their safety, quality and efficacy.

Why are a majority of the five therapeutics monoclonal antibodies?

Due to the complexity of the COVID-19 disease, a multitude of agents are under development, e.g. antivirals, immuno-modulators, anti-inflammatory agents. Candidates include small molecules, monoclonal antibodies as well as cell-based therapies. Ongoing clinical trials look at the safety and efficacy of products under development in different stages of disease: e.g. early, mild, moderate, severe COVID-19 disease; and in different patient subpopulations: ambulatory and hospitalised patients; people exposed to infection and long COVID sufferers.

Four therapeutics currently under rolling review by the EMA are antiviral monoclonal antibodies, targeting a protein (spike protein) on the surface of the SARS-CoV-2 virus that causes COVID-19, preventing the virus to enter the body's cells. Their inclusion in the rolling review procedure has been based on the promising preliminary results from clinical studies. Different to monoclonal antibodies, baricitinib is an immunosuppressant (a medicine that reduces the activity of the immune system), currently authorised for use in adults with moderate to severe rheumatoid arthritis or atopic dermatitis.

What are you doing on joint procurement?

On 8 October 2020, the Commission signed a joint procurement framework contract with the pharmaceutical company Gilead for the supply of up to 500 000 treatment courses of remdesivir, the only medicine with an EU wide conditional marketing authorisation in for the treatment of COVID-19 patients needing oxygen supply. All participating countries were able to place their orders to procure remdesivir directly. The Commission also purchased and distributed to Member States doses for a total of €70 million. Since late October 2020, the Commission has signed over 70 joint procurement contracts for 19 medicines (analgesics, antibiotics, muscle relaxers, anaesthetics, resuscitation), including dexamethasone, to treat more severe COVID-19 cases in Intensive Care Units.

A joint procurement contract for the combination product consisting of casirivimab and imdevimab was signed in April 2021 and negotiations regarding the joint procurement of other monoclonal antibodies are ongoing.

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