



COVID-19 Therapeutics Strategy: Commission identifies five promising candidate therapeutics

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The EU Strategy on COVID-19 Therapeutics delivers today its first outcome, with the announcement of the first portfolio of five therapeutics that could soon be available to treat patients across the EU. Four of these therapeutics are monoclonal antibodies under rolling review by the European Medicines Agency. Another one is an immunosuppressant, which has a marketing authorisation that could be extended to include the treatment of COVID-19 patients.

Commissioner for Health and Food Safety, Stella **Kyriakides**, said: *"Today we are taking the first step towards a broad portfolio of therapeutics to treat COVID-19. Whilst vaccination is progressing at increasing speed, the virus will not disappear and patients will need safe and effective treatments to reduce the burden of COVID-19. Our goal is clear, we aim to identify more front-runner candidates under development and authorise at least three new therapeutics by the end of the year. This is the European Health Union in action."*

The five products are in an advanced stage of development and have a high potential to be among the three new COVID-19 therapeutics to receive authorisation by October 2021, the target set under the Strategy, provided the final data demonstrate their safety, quality and efficacy. The products are:

A new COVID-19 indication for existing medicines:

- baricitinib immunosuppressant (a medicine that reduces the activity of the immune system) from Eli Lilly: an application for extension of marketing authorisation for COVID-19 indication is under assessment

Newly developed monoclonal antibodies under rolling review - a regulatory tool to speed up the assessment of a promising medicine during a public health emergency:

- combination of bamlanivimab and etesevimab from Eli Lilly: under rolling review
- combination of casirivimab and imdevimab from Regeneron Pharmaceuticals, Inc. and F. Hoffman-La Roche, Ltd: under rolling review
- regdanivimab from Celltrion: under rolling review
- sotrovimab from GlaxoSmithKline and Vir Biotechnology, Inc.: under rolling review

Next Steps

The Commission will draw up a portfolio of at least 10 potential COVID-19 therapeutics by October, building on the work of the newly established expert group on COVID-19 variants. The selection process will be objective and science based, with selection criteria 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 based on science based criteria.

The portfolio will contribute to the objective of having at least three new therapeutics authorised by October and possibly two more by the end of the year. The European Medicines Agency will start more rolling reviews of promising therapeutics by end-2021, subject to research and development outcomes.

The Commission recently concluded a joint procurement of monoclonal antibodies (casirivimab and imdevimab) and could launch more by the end of the year.

The first industry matchmaking event on therapeutics will be organised on the 12-13 July to ensure that once authorised therapeutics are produced in sufficient quantity as soon as possible.

Background

The [EU Strategy on COVID-19 Therapeutics](#) aims to build a broad portfolio of COVID-19 therapeutics with the goal of having three new therapeutics available by October 2021 and possibly two more by

the end of the year. It covers the full lifecycle of medicines from research, development, selection of promising candidates, fast regulatory approval, manufacturing and deployment to final use.

The Strategy forms part of a strong [European Health Union](#), using a coordinated EU approach to better protect the health of our citizens, equip the EU and its Member States to better prevent and address future pandemics, and improve resilience of Europe's health systems.

The Strategy, which focuses on the treatment of patients with COVID-19, works alongside the successful [EU Vaccines Strategy](#), through which safe and effective vaccines against COVID-19 have been authorised for use in the EU to prevent and reduce transmission of cases, as well as hospitalisation rates and deaths caused by the disease.

More information

[Questions and Answers: COVID-19 Therapeutics Strategy – list of 5 candidate therapeutics](#)

[European Commission's coronavirus response: therapeutics](#)

[Therapeutics Strategy](#)

[European Medicines Agency – COVID-19 therapeutics](#)

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