European Commission - Press release





European Health Union: Commission establishes portfolio of 10 most promising treatments for COVID-19

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Delivering on a key action from the EU Strategy on COVID-19 Therapeutics, the Commission is today establishing a portfolio of 10 potential COVID-19 therapeutics. The list established is based on independent scientific advice, and focuses on COVID-19 treatment candidates that are likely to be authorised and therefore available on the European market soon. These therapeutics will bring treatment to patients across the EU as fast as possible provided that their safety and effectiveness has been confirmed by the European Medicines Agency.

Vaccination against COVID-19 offers the best preventive protection against infection, severe disease, loss of life and long-term consequences of illness. While vaccination offers the best way to end the pandemic and get back to normal life, in parallel, we are ensuring that the COVID-19 therapeutics are available to treat those who are infected.

Vice-President for Promoting our European Way of Life, Margaritis **Schinas** said: "As we continue to face the challenge of COVID-19, it is important to shield ourselves in addition to vaccination. The establishment of 10 COVID-19 therapeutics will ensure that citizens receive the most promising treatments against the virus."

Commissioner for Health and Food Safety, Stella **Kyriakides**, said: "Vaccination is the only tool to prevent COVID hospitalisations and deaths, and as such, it is the only way out of this pandemic. In the meantime however, COVID-19 patients do need safe and effective treatments to fight the infection, improve their prospect of a swift recovery, reduce hospitalisations and most importantly, to prevent loss of life. We have already signed four joint procurement contracts for different COVID-19 treatments and we stand ready to negotiate more. Our goal is to authorise at least three therapeutics in the coming weeks and possibly two more by the end of the year and help Member States gain access to them as soon as possible."

The EU Strategy on COVID-19 Therapeutics is an integral element of the work to build a strong European Health Union, and is modelled on the successful EU Vaccines Strategy.

A group of independent <u>scientific experts</u> has screened 82 therapeutic candidates in late stage clinical development and identified 10 candidates as the most promising for the EU portfolio of COVID-19 treatments, taking into account that different types of products are needed for different patient populations and at different stages and severity of the disease. The list of ten is divided in three categories of treatments and will continue to evolve as new scientific evidence emerges:

- Antiviral monoclonal antibodies that are most efficacious in the earliest stages of infection:
 - Ronapreve, a combination of two monocolonal antibodies casirivimab and imdevimab from Regeneron Pharmaceuticals and Roche.
 - Xevudy (sotrovimab) from Vir Biotechnology and GlaxoSmithKline.
 - Evusheld, a combination of two monoclonal antibodies tixagevimab and cilgavimab from AstraZeneca.
- Oral antivirals for use as quickly as possible after the infection:
 - Molnupiravir from Ridgeback Biotherapeutics and MSD.
 - o PF-07321332 from Pfizer.
 - AT-527 from Atea Pharmaceuticals and Roche.
- Immunomodulators to treat hospitalised patients:
 - o Actemra (tocilizumab) from Roche Holding.
 - Kineret (anakinra) from Swedish Orphan Biovitrum.
 - Olumiant (baricitinib) from Eli Lilly.

• Lenzilumab from Humanigen.

Next Steps

Six of the <u>selected therapeutics</u> are already under rolling review or have applied for marketing authorisation to the European Medicines Agency. They could receive authorisation soon, provided the final data demonstrate their quality, safety, and efficacy.

The selection of the 10 candidates is independent from and does not replace the scientific assessment by the European Medicines Agency or the authorisation of the medicines by the European Commission. A selected product may not be authorised, if the available scientific evidence does not meet the regulatory requirements.

The four other candidates on the list all received scientific advice from EMA, and once enough clinical data is collected, further rolling reviews can start.

As announced in the Therapeutics Strategy, an innovation booster will support those therapeutics at earlier stages of development.

The Health Emergency Preparedness and Response Authority (HERA) will set up an interactive mapping platform for promising therapeutics. A call for tender to design the platform has been launched.

In November, a pan-European matchmaking event for therapeutics industrial production will be organised to help accelerate the development of new and repurposed medicines for COVID-19 therapeutics and mobilise the EU's pharmaceutical manufacturing capacity.

Background

The <u>EU strategy on COVID-19 therapeutics</u> complements the <u>EU Vaccines Strategy</u>, which remains the EU's primary tool for ending the pandemic by preventing and reducing transmission of cases, as well as hospitalisation rates and deaths caused by the disease.

The Therapeutics Strategy aims to build a broad portfolio of COVID-19 therapeutics with the goal of having three to five new therapeutics available 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. A first list of <u>five promising therapeutics</u> was published in June 2021.

The Strategy forms part of a strong <u>European Health Union</u>, 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.

More information

Questions and Answers: list of ten most promising therapeutics

Report of the Covid-19 therapeutics sub-group: Covid-19 therapeutics portfolio – list of ten most promising candidates

European Commission's coronavirus response: therapeutics

European Medicines Agency - COVID-19 therapeutics

Feasibility study, Design and Prototype Development for a Mapping Platform on COVID-19 Therapeutics in the EU

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