Roche applies to market COVID antibody treatment in EU

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Swiss pharma giant Roche on Monday applied to market its anti-COVID-19 cocktail in the European Union, the bloc's medicines watchdog said, the final step before it can be released to the continent.

The application to the European Medicines Agency comes just over two

weeks after the World Health Organisation also recommended the treatment, which Roche co-developed with US biotech firm Regeneron.

The "EMA is starting evaluating an application for marketing authorisation for the monoclonal antibody combination Ronapreve (casirivimab/imdevimab)," the Amsterdam-based watchdog said.

A speeded-up process means the EMA "could issue an opinion within two months," it added.

Monoclonal antibodies—which recognise a specific molecule of the target virus or bacteria—are synthetic copies of those natural proteins that can be reproduced and administered as a treatment.

This is different from a vaccine, which stimulates the body to produce its own immune response.

Synthetic antibodies are administered to people already infected, to make up for deficiencies in the immune system.

Ronapreve "is intended for the treatment of COVID-19 in adults and adolescents from 12 years of age who do not require supplemental oxygen therapy" and risked getting a severe form of the disease.

It is also used "for the prevention of COVID-19 in adults and adolescents aged 12 and older," the EMA said.

Designed by Regeneron and marketed by Roche, Ronapreve treatment was given to former US president Donald Trump during his brush with coronavirus.

An application for marketing authorisation is the last stage in which the EMA's human medicines committee does a final scientific evaluation

before making a recommendation to the European Commission, who can then give its release the thumbs-up.

Two weeks ago the WHO also backed the treatment but only in patients with specific health profiles.

Persons with non-severe COVID-19 who are nonetheless at high risk of hospitalisation can take the antibodies, as should critically ill patients unable to mount an adequate immune response, the WHO said in a finding published in the *BMJ*.

The cocktail is only the third treatment for COVID recommended by the global health authority.

So far, the only treatment authorised for use in Europe is remdesivir, marketed as Veklury, a so-called viral RNA polymerase inhibitor which interferes with the production of viral genetic material, preventing the virus from multiplying inside cells.