FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
onlus

COVID-19 authorised medicines

The **Human Medicines Committee (CHMP) at EMA** assessed the use of the following medicines to treat COVID-19

Treatment	Description	Status	Target population	Date of approval	PIP number	More information
Xevudy (sotrovimab)	Sotrovimab is a monoclonal antibody designed to attach to the Spike protein of SARS-CoV-2. When it attaches to the Spike protein, the ability of the virus to enter the body's cells is reduced	Marketing authorisation granted	Adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of the disease becoming severe	December 2021	-	https://www.ema.europa.eu/en/news/covid-19-ema-recommends-authorisation-antibody-medicine-xevudy
Kineret (anakinra)	Kineret is an immunosuppressant currently authorised for the treatment of several inflammatory conditions. Its active substance, anakinra, blocks the activity of interleukin 1, a chemical messenger involved in immune processes that lead to inflammation	Marketing authorisation granted	Adult patients with pneumonia requiring supplemental oxygen and who are at risk of developing severe respiratory failure, as determined by blood levels of the suPAR protein	December 2021	-	https://www.ema.europa.eu/en/news/ema-recommends-approval-use-kineret-adults-covid-19

Treatment	Description	Status	Target population	Date of approval	PIP number	More information
RoActemra	The active substance in RoActemra, tocilizumab, is a monoclonal antibody, designed to attach to the receptor for the interleukin-6 (IL-6) which plays an important role in severe COVID-19 disease and associated respiratory failure. By preventing IL-6, RoActemra reduces the inflammation and improves symptoms of severe COVID-19	Marketing authorisation for COVID-19 indication granted	Adults with COVID-19 who are receiving systemic treatment with corticosteroids and require supplemental oxygen or mechanical ventilation	December 2021	-	https://www.ema.europa.eu/en/news/ema-recommends-approval-use-roactemra-adults-severe-covid-19
Ronapreve (casirivimab/ imdevimab)	This medicine is made of casirivimab and imdevimab, two monoclonal antibodies. Casirivimab and imdevimab have been designed to attach to the	Marketing authorisation granted	Adults and adolescents (from 12 years of age and weighing at least 40 kilograms) who do not require supplemental oxygen and who are at increased risk of their	November 2021	-	https://www.ema.europa.eu/en/news/covid-19-ema-recommends-authorisation-two-monoclonal-antibody-medicines

Treatment	Description	Status	Target population	Date of approval	PIP number	More information
	Spike protein of SARS-CoV-2 at two different sites. When the antibodies are attached to the Spike protein, the virus is unable to enter the human cells		disease becoming severe			
Regkirona (regdanvimab)	Regdanvimab is a monoclonal antibody that has been designed to attach to the Spike protein of SARS-CoV-2. When it attaches to the Spike protein, the ability of the virus to enter the body's cells is reduced	Marketing authorisation granted	Adults with COVID-19 who do not require supplemental oxygen and who are also at increased risk of their disease becoming severe	November 2021	EMEA-002961-PIP01-21	https://www.ema.europa.eu/en/news/covid-19-ema-recommends-authorisation-two-monoclonal-antibody-medicines

Treatment	Description	Status	Target population	Date of approval	PIP number	More information
Veklury (Remdesivir)	Veklury is an antiviral. It is a viral RNA polymerase inhibitor and interferes with the production of viral RNA, preventing the virus from multiplying inside cells	Conditional marketing authorisation through a rolling review procedure	Adults and adolescents (from 12 years of age and weighing at least 40 kilograms) with pneumonia requiring supplemental oxygen	July 2020	EMEA-002826-PIP01-20-M01	https://www.ema.europa.eu/en/medicines/human/EPAR/veklury