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EMA starts evaluating the use of Kineret in adult COVID-19 patients at increased risk of severe respiratory failure

EMA has started evaluating an application to extend the use of Kineret (anakinra) to include treatment of coronavirus disease 2019 (COVID-19) in adult patients with pneumonia who are at risk of developing severe respiratory failure (inability of the lungs to work properly).

Kineret is an immunosuppressant (a medicine that reduces the activity of the immune system) currently authorised for the treatment of a number of inflammatory conditions. Its active substance, anakinra, blocks the activity of interleukin 1, a chemical messenger involved in immune processes that lead to inflammation. It is thought that this could also help reduce the inflammation and tissue damage associated with COVID-19.

EMA's human medicines committee (CHMP) will assess data submitted in the application to decide whether to recommend the extension of indication. Data submitted include results from two ongoing clinical studies investigating the safety and efficacy of the medicine in adult patients hospitalised with COVID-19.

The CHMP's opinion, together with any requirements for further studies and additional safety monitoring, will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

EMA will communicate on the outcome of its evaluation, which is expected by October unless supplementary information is needed.

Kineret has been authorised in the EU since March 2002. More information about the medicine is available on the EMA website.

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