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EMA recommends approval for use of Kineret in adults with COVID-19

EMA's human medicines committee (CHMP) has recommended extending the indication of Kineret (anakinra) to include treatment of COVID-19 in adult patients with pneumonia requiring supplemental oxygen (low or high flow oxygen) and who are at risk of developing severe respiratory failure, as determined by blood levels of a protein called suPAR (soluble urokinase plasminogen activator receptor) of at least 6 ng per ml.

Kineret, marketed by Swedish Orphan Biovitrum AB (publ), is an immunosuppressive medicine (meaning it reduces the activity of the immune system). It is currently authorised in the EU for the treatment of various inflammatory conditions. In COVID-19 patients, the medicine is considered to reduce the inflammation associated with the disease and thus decrease lower airway damage, preventing development of severe respiratory failure.

Study data in COVID-19

In reaching its conclusion, the CHMP evaluated data from a study involving 606 hospitalised adults with moderate or severe COVID-19 pneumonia and who had suPAR levels of at least 6 ng per ml. These patients received Kineret or placebo (a dummy treatment) by injection under the skin in addition to standard of care. Standard of care for most patients included low or high flow oxygen and the corticosteroid medicine dexamethasone, and some also received remdesivir.

The study showed greater clinical symptom improvements in patients treated with Kineret plus standard of care compared with those who received placebo plus standard of care. Kineret reduced the risk of a patient's condition worsening to more severe disease or death during the 28-day study period compared with placebo. The treatment benefit of Kineret compared to placebo was supported by an increase in the number of patients who fully recovered and a reduction in the number of patients whose condition worsened to severe respiratory failure or death.

The study also indicated that Kineret's safety in patients with COVID-19 was similar to that seen in patients treated for the other approved indications. As such, the CHMP concluded that the medicine's benefits are greater than the risks for patients like those studied in this clinical trial. Efficacy of Kineret has not been shown in patients requiring non-invasive or mechanical ventilation or extracorporeal membrane oxygenation (a heart-lung bypass life support system).

More about Kineret

Kineret is a medicine currently authorised in the EU to treat the immune disorders rheumatoid arthritis and Still's disease, as well as the autoinflammatory periodic fever syndromes cryopyrin-associated periodic syndromes (CAPS) and familial Mediterranean fever. The active substance in Kineret, anakinra, is an immunosuppressive medicine. It works by preventing the action of interleukin 1, a chemical messenger involved in immune processes that lead to inflammation. This messenger is involved in the inflammatory processes associated with the diseases Kineret is used to treat. By attaching to the receptors (targets on cells) that interleukin 1 would normally attach itself to, anakinra blocks the activity of interleukin 1, helping to relieve the symptoms of these diseases.

More information about the evaluation of Kineret and the approved product information is available on EMA's medicine page for Kineret.

The CHMP will now send its recommendation for COVID-19 to the European Commission, which will issue a final decision.