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

EMA's human medicines committee (CHMP) has recommended extending the indication of RoActemra (tocilizumab) to include the treatment of adults with COVID-19 who are receiving systemic treatment with corticosteroids and require supplemental oxygen or mechanical ventilation.

The medicine, marketed by Roche Registration GmbH, is already approved in the EU for treating the inflammatory conditions rheumatoid arthritis, systemic juvenile idiopathic arthritis, juvenile idiopathic polyarthritis, giant cell arteritis and cytokine release syndrome (CRS).

Study data in COVID-19

In reaching its conclusion, the CHMP evaluated data from a main study involving 4,116 hospitalised adults with severe COVID-19 who required extra oxygen or mechanical ventilation and had high levels of C-reactive protein in the blood (indicating inflammation).

The study showed that treatment with RoActemra given by infusion in addition to standard treatment reduces the risk of death when compared with standard treatment alone. Overall 31% of patients treated with RoActemra plus standard treatment (621 out of 2,022) died within 28 days of treatment compared with 35% of patients receiving standard treatment alone (729 out of 2,094). In addition, 57% of patients (1,150 out of 2,022) who received RoActemra were able to leave the hospital within 28 days compared with 50% of patients (1,044 out of 2,094) who received standard treatment alone.

The study also indicated that an increase in mortality cannot be excluded when using RoActemra in patients who are not receiving systemic corticosteroids. However, the safety profile of the medicine was favourable in those who are already receiving treatment with corticosteroids and the CHMP concluded that the medicine's benefits are greater than the risks for these patients.

More about RoActemra

RoActemra is an immunomodulating medicine (a medicine that changes the immune system activity). The active substance in RoActemra, tocilizumab, is a monoclonal antibody, a type of protein designed to attach to a specific target (called an antigen) in the body. RoActemra attaches to the receptor for a messenger molecule or 'cytokine' called interleukin-6 (IL-6). IL-6 is produced by the body's immune system in response to systemic inflammation (inflammation throughout the body), which plays an important role in severe COVID-19 disease and associated respiratory failure. By preventing IL-6 from attaching to its receptors, RoActemra reduces the inflammation and improves symptoms of severe COVID-19.

More information about the evaluation of RoActemra and the approved product information are available on the medicines page for RoActemra on EMA's website.

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