12 December 2024
EMA/CHMP/546116/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Avtozma

tocilizumab

On 12 December 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Avtozma, intended for the treatment of rheumatoid arthritis (RA), systemic juvenile idiopathic arthritis (sJIA), polyarticular juvenile idiopathic arthritis (pJIA), giant cell arteritis (GCA), CAR-T cell-induced severe or life-threatening cytokine release syndrome (CRS) and coronavirus disease 2019 (COVID-19).

The applicant for this medicinal product is Celltrion Healthcare Hungary Kft.

Avtozma will be available as 20 mg/ml concentrate for solution for infusion and a 162 mg solution for injection in pre-filled syringe or pre-filled pen. The active substance of Avtozma is tocilizumab, an interleukin inhibitor (ATC code: L04AC07). Tocilizumab is a recombinant humanised anti-human interleukin-6 receptor (IL-6R) monoclonal antibody of the immunoglobulin IgG1 subclass. It works by inhibiting soluble and membrane-bound interleukin-6 receptors involved in the pathogenesis of inflammatory diseases.

Avtozma is a biosimilar medicinal product. It is highly similar to the reference product RoActemra (tocilizumab), which was authorised in the EU on 16 January 2009. Data show that Avtozma has comparable quality, safety and efficacy to RoActemra (tocilizumab). More information on biosimilar medicines can be found here.

The full indication for Avtozma 20 mg/mL concentrate for solution for infusion is:

> Avtozma, in combination with methotrexate (MTX), is indicated for:
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> - the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
> - the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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In these patients, Avtozma can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Avtozma has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Avtozma is indicated for the treatment of coronavirus disease 2019 (COVID-19) in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

Avtozma is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 2 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Avtozma can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

Avtozma in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Avtozma can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Avtozma is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older.

The full indication for Avtozma 162 mg solution for injection in pre-filled syringe is:

Avtozma, in combination with methotrexate (MTX), is indicated for

- the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, Avtozma can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Avtozma has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Avtozma is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Avtozma can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

Avtozma in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Avtozma can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Avtozma is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

The full indication for Avtozma 162 mg solution for injection in pre-filled pen is:

Avtozma, in combination with methotrexate (MTX), is indicated for

- the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- the treatment of moderate to severe active RA in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.

In these patients, Avtozma can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Avtozma has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.

Avtozma is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 12 years of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids (see Section 4.2). Avtozma can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

Avtozma in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 12 years of age and older, who have responded inadequately to previous therapy with MTX (see Section 4.2). Avtozma can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.

Avtozma is indicated for the treatment of Giant Cell Arteritis (GCA) in adult patients.

Treatment should be initiated by healthcare professionals experienced in the diagnosis and treatment of RA, COVID-19, sJIA, pJIA, CRS, and/or GCA. All patients treated with Avtozma should be given the patient alert card.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.