

17 October 2024  
EMA/CHMP/453178/2024  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Kevzara sarilumab

On 17 October 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Kevzara. The marketing authorisation holder for this medicinal product is Sanofi Winthrop Industrie.

The CHMP adopted a new indication as follows:

#### Polymyalgia rheumatica

Kevzara is indicated for the treatment of polymyalgia rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper.

For information, the full indications for Kevzara will be as follows:<sup>2</sup>

#### Rheumatoid arthritis

Kevzara in combination with methotrexate (MTX) is indicated for the treatment of moderately to severely active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Kevzara can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate (see section 5.1).

#### Polymyalgia rheumatica

Kevzara is indicated for the treatment of polymyalgia rheumatica (PMR) in adult patients who have had an inadequate response to corticosteroids or who experience a relapse during corticosteroid taper.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and made available in all official European Union languages after a decision on this change to the

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

<sup>2</sup> New text in bold

marketing authorisation has been granted by the European Commission.