



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

24 June 2021  
EMA/CHMP/336023/2021  
Committee for Medicinal Products for Human Use (CHMP)

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

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### Bimzelx

#### bimekizumab

On 24 June 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Bimzelx, intended for the treatment of moderate to severe plaque psoriasis.

The applicant for this medicinal product is UCB Pharma S.A.

Bimzelx will be available as a 160 mg solution for injection. The active substance of Bimzelx is bimekizumab, a recombinant humanised IgG1 monoclonal antibody (ATC code: L04AC21) that works by inhibiting interleukin (IL)-17A and IL-17F signalling.

The benefits of Bimzelx are its ability to improve the skin condition as measured by improvements in the Investigator's Global Assessment (IGA) 0/1 and Psoriasis Area and Severity Index 90 (PASI 90) response and to reduce itching, pain and scaling of the skin in patients with plaque psoriasis. The most common side effects are upper respiratory tract infections and oral candidiasis.

The full indication is:

Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Bimzelx should be prescribed by physicians experienced in the treatment of plaque psoriasis.

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.

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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

