25 April 2025
EMA/CHMP/90149/2025
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Duvyzat

givinostat

On 25 April 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Duvyzat[3], intended for the treatment of Duchenne muscular dystrophy (DMD).

The applicant for this medicinal product is Italfarmaco S.p.A.

Duvyzat will be available as an 8.86 mg/ml oral suspension. The active substance of Duvyzat is givinostat, a drug for disorders of the musculoskeletal system (ATC code: M09AX14). Givinostat is a class I and II histone deacetylase (HDAC) inhibitor which modulates the uncontrolled activity of HDAC in dystrophic muscles, reducing muscle fibre damage, chronic muscular inflammation, fibrosis and fat deposition while promoting the production of new mitochondria.

The benefit of Duvyzat was shown in a phase 3 clinical study involving ambulant children with DMD aged 6 years and older. In this study, patients receiving Duvyzat on top of corticosteroids maintained mobility longer compared to patients receiving placebo and corticosteroids, as measured by a reduction in the time needed to complete the 4-stair climb (4SC) test after 18 months of treatment. The most common side effects with Duvyzat include diarrhoea, abdominal pain, thrombocytopenia, vomiting, hypertriglyceridaemia and fever.

The full indication of Duvyzat is:

> Duvyzat is indicated for the treatment of Duchenne muscular dystrophy (DMD) in ambulant patients, aged 6 years and older, and with concomitant corticosteroid treatment.

Duvyzat should be prescribed by physicians experienced in the treatment of Duchenne muscular dystrophy.

[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
[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is expected to provide comprehensive clinical data at a later stage.
[3] This product was designated as an orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after the marketing authorisation has been granted by the European Commission.