27 June 2024
EMA/290325/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Piasky

crovalimab

On 27 June 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 Piasky, intended as monotherapy for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH). The applicant for this medicinal product is Roche Registration GmbH.

Piasky will be available as a 340 mg solution for injection/infusion. The active substance of Piasky is crovalimab, a complement inhibitor (ATC code: L04AJ07). Crovalimab binds to C5 to prevent its cleavage, thus preventing the formation of the membrane attack complex (MAC). This inhibits terminal complement-mediated intravascular haemolysis.

The benefit of Piasky is haemolysis control and transfusion avoidance, as observed in a phase III, multicentre, open-label study comparing crovalimab and eculizumab in patients with PNH who were not previously treated with a complement-inhibitor. The benefit of Piasky is demonstrated also in clinically stable patients switching from another complement component 5 inhibitor therapy. The most common side effects are type III immune complex mediated reaction, upper respiratory tract infection, pyrexia, headache and infusion related reaction.

The full indication is:

> Piasky as monotherapy is indicated for the treatment of adult and paediatric patients 12 years of age or older with a weight of 40 kg and above with paroxysmal nocturnal haemoglobinuria (PNH):
>
> - In patients with haemolysis with clinical symptom(s) indicative of high disease activity.
> - In patients who are clinically stable after having been treated with a complement component 5 (C5) inhibitor for at least the past 6 months.

Treatment should be initiated under the supervision of a physician experienced in the treatment of haematological disorders.

[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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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.