28 June 2018
EMA/CHMP/419463/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Cablivi

caplacizumab

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Cablivi, intended for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP). Cablivi was designated as an orphan medicinal product on 30 April 2009. The applicant for this medicinal product is Ablynx NV.

Cablivi will be available as a 10 mg powder and solvent for solution for injection. The active substance of Cablivi is caplacizumab, a humanised bivalent nanobody that inhibits the interaction between von Willebrand factor and platelets (ATC code: B01AX07). As a result, caplacizumab prevents von Willebrand factor-mediated platelet adhesion, which is characteristic of aTTP. It also affects the disposition of von Willebrand factor, leading to transient reductions of total von Willebrand factor antigen levels and to concomitant reduction of factor VIII:C levels during treatment.

The benefits with Cablivi are its ability to reduce time to platelet count response, the recurrence rate of the disease, the number of days of plasma exchange, the volume of plasma used, and the length of hospitalization and intensive care unit stay. The most common side effects are bleedings. Other most common adverse reactions were pyrexia, fatigue, headache, urticaria, injection site reaction, myalgia, injection site pruritus, injection site erythema, cerebral infarction, dyspnoea.

The full indication is: "Cablivi is indicated for the treatment of adults experiencing an episode of acquired thrombotic thrombocytopenic purpura (aTTP), in conjunction with plasma exchange and immunosuppression."

It is proposed that Cablivi be prescribed and supervised by physicians experienced in the treatment of management of patients with thrombotic microangiopathies.

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.

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact