18 November 2021
EMA/529577/2021

EMA receives application for marketing authorisation for Xevudy (sotrovimab) for treating patients with COVID-19

EMA has started evaluating an application for marketing authorisation for the monoclonal antibody Xevudy (sotrovimab). The applicant is GlaxoSmithKline Trading Services Limited, who developed the medicine together with Vir Biotechnology.

Xevudy is intended for the treatment of adults and adolescents with COVID-19 who do not require supplemental oxygen therapy and who are at increased risk of progressing to severe COVID-19.

EMA will assess the benefits and risks of Xevudy under a reduced timeline and could issue an opinion within two months, depending on whether the data submitted are sufficiently robust and whether further information is required to support the evaluation.

Such a short timeframe is only possible because EMA's human medicines committee (CHMP) has already reviewed some data on the medicine during a rolling review. During this phase, CHMP assessed data from laboratory studies and animal studies, as well as data on the quality of the medicine. In addition, CHMP assessed data from a study into the effects of sotrovimab in adult outpatients with mild COVID-19 symptoms who do not need supplemental oxygen and who are at increased risk of their disease becoming severe.[1]

In parallel, EMA's safety committee (PRAC) completed the preliminary assessment of the risk management plan (RMP) proposed by the company, which outlines measures to identify, characterise and minimise the medicine's risks. Furthermore, EMA's committee for medicines for children (PDCO) issued its opinion on the company's paediatric investigation plan (PIP), which describes how the medicine should be developed and studied for use in children, in accordance with the accelerated timelines for COVID-19 products.

Should the additional data now submitted with the marketing authorisation application be sufficient for CHMP to conclude that the benefits of Xevudy outweigh its risks in the treatment of COVID-19, EMA will liaise closely with the European Commission to fast track the decision granting a marketing authorisation in all EU and EEA Member States.

EMA will communicate further at the time of the CHMP's opinion.

[1] Based on an interim analysis of this study EMA issued advice on the use of sotrovimab for treating COVID-19 in May 2021.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How is the medicine expected to work?

Sotrovimab (also known as VIR-7831 and GSK4182136) is a monoclonal antibody with activity against COVID-19. A monoclonal antibody is a type of protein that attaches to a specific structure (called an antigen). Sotrovimab is designed to attach to the spike protein of SARS-CoV-2, the virus that causes COVID-19. When it attaches to the spike protein, the ability of the virus to enter the body's cells is reduced. This is expected to reduce the severity of the disease and the need for hospitalisation in patients with COVID-19.