EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency maintains recommendation not to grant a marketing authorisation for Glybera

Insufficient evidence to show benefit of Glybera in lipoprotein lipase deficiency patients with severe or multiple pancreatitis attacks

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) at its April 2012 meeting maintained its recommendation not to grant a marketing authorisation for the orphan medicine Glybera (alipogene tiparvovec), from Amsterdam Molecular Therapeutics B.V.

This followed a request of the European Commission in January 2012 to review the benefit risk of Glybera in a restricted group of patients with severe or multiple pancreatitis attacks.

Glybera is a gene-therapy product using an adeno-associated viral vector and was intended for the treatment of adult patients diagnosed with lipoprotein lipase deficiency demonstrating hyperchylomicronaemia or having a history of acute pancreatitis.

When evaluating Glybera in patients with severe or multiple pancreatitis attacks, the CHMP concluded that the evidence that Glybera reduced pancreatitis attacks in the small number of patients assessed (data from only 12 patients were available) was not sufficiently convincing. In addition, the reduced risk of pancreatitis seen in a few of the patients could have been due to other factors (such as changes in lifestyle and diet, and the natural course of the disease).

In its discussions, the Committee recognised the difficulty of obtaining and assessing data in this very rare disease. However, after careful consideration of all the evidence and circumstances of the disease, the Committee maintained its previous recommendation not to grant a marketing authorisation.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The CHMP issued an initial recommendation recommending not to grant a marketing authorisation for Glybera in June 2011.

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3. The negative opinion was confirmed in October 2011, following a re-examination requested by the applicant.
4. A question-and-answer document on this procedure is available on the Agency's website.
5. The Committee's recommendation has now been forwarded to the European Commission for a final decision.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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