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Press Office

Press release

European Medicines Agency advises on compassionate use of daclatasvir

Opinion concerns use in combination with sofosbuvir in patients with chronic hepatitis C in urgent need of therapy to prevent progression of liver disease

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has given an opinion on the use of daclatasvir in combination with sofosbuvir in the treatment of chronic (long-term) hepatitis C virus (HCV) infection, in a compassionate-use programme.

Compassionate-use programmes are set up at the level of individual Member States. They are intended to give patients with a life-threatening, long-lasting or seriously disabling disease with no available treatment options access to treatments that are still under development and that have not yet received a marketing authorisation. In this specific case, Sweden has requested an opinion from the CHMP on the conditions under which early access through compassionate use could be given to daclatasvir, for the use in combination with sofosbuvir, with or without ribavirin, for a specific patient population.

The recommended compassionate use is intended for adult patients at a high risk of their liver being no longer able to function normally (decompensation) or death within 12 months if left untreated, and who have a genotype 1 infection. Further, it is recognised that the potential benefit of such combination therapy may extend to patients infected with other HCV genotypes.

Daclatasvir and sofosbuvir are both first-in-class anti-viral medicines against HCV. These medicines have been studied in combination, with or without ribavirin, in a clinical trial which included treatment-naive (previously untreated) HCV genotype-1, -2 and -3 infected patients, as well as patients with genotype 1 infection who have previously failed telaprevir or boceprevir treatment. Results from the trial indicate high efficacy, also in those who have failed treatment with these protease inhibitors. Many such patients have very advanced liver disease and are in urgent need of effective therapy in order to cease the progression of liver injury.

This is the second opinion provided by the CHMP on compassionate use of medicines in development for the treatment of hepatitis C. Overall, it is the fourth time compassionate use has been assessed by the CHMP.

The aim of the CHMP assessment and opinion on a compassionate-use programme for new medicinal products is to ensure a common approach, whenever possible, regarding the criteria and conditions of

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use under Member States' legislation. The opinion provides recommendations to the EU Member States that are considering setting up such a programme, and its implementation is not mandatory. In addition to describing which patients may benefit from the medicine, it explains how to use it and gives information on safety.

The assessment report and conditions of use of daclatasvir in combination with sofosbuvir with or without ribavirin in this setting will be published shortly on the Agency's website.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The first compassionate-use opinion for a hepatitis C treatment was adopted by the CHMP in October 2013. More information is available in a press release here : http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/10/WC500153144.pdf
3. Sofosbuvir, which is part of this compassionate-use opinion, received a positive opinion from the CHMP recommending granting of a marketing authorisation at its November 2013 meeting.
4. Daclatasvir is developed by Bristol-Myers Squibb and sofosbuvir is developed by Gilead.
5. A question-and-answer document on the compassionate use of medicines in the European Union can be found here: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/01/WC500069898.pdf
6. More information on compassionate use and programmes already assessed can be found here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000293.jsp&mid=WC0b01ac058007e691
7. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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