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Press Office

Press release

European Medicines Agency advises on compassionate use of a new combination therapy for chronic hepatitis C

Combination of ledipasvir and sofosbuvir to be used in patients 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 a fixed-dose combination of ledipasvir and 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 requested an opinion from the CHMP on the conditions under which early access through compassionate use could be given to a combination of ledipasvir and sofosbuvir, with or without ribavirin, for adult patients with genotype 1 HCV infection and advanced liver disease, who are at a high risk of their liver being no longer able to function normally (decompensation) or death within 12 months if left untreated.

In clinical trials, the combination of ledipasvir and sofosbuvir, with or without ribavirin, used for 12 or 24 weeks, has shown high efficacy in treating patients with genotype 1 virus, including patients with compensated cirrhosis (scarring of the liver but normal liver function) and patients who have previously failed treatment with the protease inhibitors telaprevir or boceprevir (other treatments for hepatitis C). Many of these patients have very advanced liver disease and are in urgent need of effective therapy in order to halt the progression of liver injury.

This is the third opinion provided by the CHMP since October 2013 on compassionate use of medicines in development for the treatment of hepatitis C.

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 their use prior to their authorisation under Member States' legislation. The opinion provides recommendations to the EU Member States that are considering setting up such a programme, and its

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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 the combination of ledipasvir and 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 fixed-dose combination of ledipasvir and sofosbuvir is being developed by Gilead Sciences.
3. Sofosbuvir, which is part of this compassionate-use opinion, was granted a marketing authorisation valid throughout the European Union on 16 January 2014. More information on this medicine, called Sovaldi, is available here: http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/002798/human_med_001723.jsp&mid=WC0b01ac058001d124
4. 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
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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