EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2014
EMA/584056/2014
Press Office

Press release

Harvoni recommended for the treatment of chronic hepatitis C

Growing number of treatment options improve patients' chances of longer and healthier lives

The European Medicines Agency has recommended the authorisation of Harvoni (ledipasvir / sofosbuvir) for the treatment of chronic hepatitis C virus (HCV) infection in adults.

HCV infection is a major European public-health challenge. It affects between 0.4% and 3.5% of the population in different European Union (EU) Member States and is the most common single cause of liver transplantation in the EU.

Harvoni belongs to a new generation of antiviral products for chronic HCV infection that have high cure rates and have recently reshaped the treatment landscape for this disease. It is a combination of the active substances sofosbuvir and ledipasvir, which block the action of proteins which are essential for HCV to replicate - the protein NS5B for sofosbuvir and NS5A for ledipasvir.

These new regimens allow cure of patients with chronic HCV infection without the need for treatments involving interferons, medicines which are associated with poor tolerability and potentially serious side effects that rule out such treatment in a considerable proportion of HCV patients.

Over the past few months, the Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisations for three new medicines for the treatment of HCV. However, in the area of HCV doctors and patients can still benefit from alternative treatment options. The more treatment options that are available, the better chance a patient has to get the right treatment to cure the disease and to lead a longer and healthier life.

Harvoni was evaluated under the EMA's accelerated assessment mechanism, a tool which aims to speed up patients' access to new medicines where there is an unmet medical need.

The opinion adopted by the CHMP at its September 2014 meeting is an intermediary step on Harvoni's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once marketing authorisation has been granted, decisions about price and reimbursement will then take place at the level of each Member

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State considering the potential role/use of this medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing authorisation applicant for Harvoni is Gilead Sciences.
3. The CHMP recommended a marketing authorisation for Sovaldi (sofosbuvir) in combination with other medicines for the treatment of chronic hepatitis C infection in November 2013: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/11/news_detail_001970.jsp&mid=WC0b01ac058004d5c1
4. The CHMP recommended a marketing authorisation for Daklinza (daclatasvir) in combination with other medicines for the treatment of chronic hepatitis C infection in June 2014: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/06/news_detail_002133.jsp&mid=WC0b01ac058004d5c1
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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