



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2017
EMA/CHMP/392513/2017
Media and Public Relations

Press release

Two new medicines recommended for the treatment of chronic hepatitis C

Maviret and Vosevi evaluated under accelerated assessment

The European Medicines Agency has recommended granting marketing authorisations in the European Union (EU) for Maviret and Vosevi, two new medicines indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults.

HCV infection is a major public health challenge. It affects between 0.4% and 3.5% of the population in different EU Member States and is the most common single cause of liver transplantation in the EU. Approximately 15 million people are chronically infected with HCV throughout Europe.

Both Maviret and Vosevi are active against all genotypes of the virus and, with some differences between the two medicines, may be specifically useful in some patients who failed or cannot use previously available therapies. As this is considered to be of major public health interest in terms of therapeutic innovation, both medicines were evaluated under the EU's accelerated assessment mechanism, which aims to speed up patients' access to new medicines where there is an unmet medical need.

Maviret and Vosevi belong to the direct acting antivirals against HCVs which have reshaped the way chronic HCV infection is treated. By blocking the action of proteins essential for HCV replication, this type of medicine achieves high cure rates of the infection and does not require the concomitant use of interferons, medicines which are associated with poor tolerability and potentially serious side effects.

Despite the rapid development of new therapies there is still a need for a range of alternative treatment options to serve the different medical needs of the millions of people suffering from the disease. 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.

Maviret and Vosevi are the first medicines for which accelerated assessment has been carried out within 120 days, after a recent review of the timetable for this mechanism.

Maviret contains two next generation direct-acting and antiviral agents: glecaprevir, an inhibitor of HCV NS3/4A protease, and pibrentasvir, an inhibitor of HCV NS5A. Both components are pangenotypic.



The effects of Maviret were studied in a total of 2,376 patients who participated in eight pivotal and three supportive clinical trials. The hepatitis C virus could no longer be detected in over 90% of patients 12 weeks after the end of treatment. If the blood of patients is clear of hepatitis C virus for more than 12 weeks they are generally considered as being cured of the infection. Adverse events reported with Maviret were generally mild, including headache, fatigue, diarrhoea, nausea and abdominal pain.

The applicant for Maviret received scientific advice from the Agency during the development of the medicine.

Vosevi is composed of sofosbuvir (a nucleotide analogue non-structural protein NS5B polymerase inhibitor), velpatasvir (an HCV NS5A inhibitor), which were previously approved in other medicinal product, to which is added voxilaprevir (a novel pangenotypic HCV NS3/4A protease inhibitor).

The effects of Vosevi were studied in four main clinical trials involving over 1,700 patients. Two studies were in previously untreated patients and two in patients in whom previous treatment (in some cases with an NS5A inhibitor) had not cleared the virus. Treatment was given for 12 weeks in the previously treated patients and eight weeks in the untreated. The hepatitis C virus could no longer be detected in over 90% of patients 12 weeks after the end of treatment with Vosevi. Mild nausea, headache and diarrhoea were the most common side effects observed. Other potentially related adverse effects were decreased appetite, vomiting, muscle spasms and rash.

The opinions adopted by the CHMP at its June 2017 meeting are an intermediary step on Maviret's and Vosevi's path to patient access. The CHMP opinions will now be sent to the European Commission for the adoption of decisions on EU-wide marketing authorisations through an accelerated procedure. Once a marketing authorisation has been granted, decisions about price and reimbursement will take place at the level of each Member State, taking into account the potential role/use of these medicines 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 applicant for Maviret is AbbVie Ltd.
3. The applicant for Vosevi is Gilead Sciences International Ltd.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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