



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends approval of sofosbuvir for the treatment of chronic hepatitis C

First-in-class medicine provides the first interferon-free treatment option

The European Medicines Agency's Committee for Medicinal Products for Human use (CHMP) has recommended granting a marketing authorisation for Sovaldi (sofosbuvir), for use 'in combination with other medicinal products for the treatment of chronic (long-term) hepatitis C in adults'.

Hepatitis C virus (HCV) infection is a major European public-health challenge. It occurs in between 0.4% and 3.5% of the population in different European Union (EU) Member States.

The current standard of care includes a combination of the medicines pegylated interferon and ribavirin, with or without an inhibitor of the viral NS3/4A protease enzyme. However, interferon-based therapies are associated with potentially serious side effects, which are sometimes difficult to manage and also make a considerable proportion of HCV patients ineligible for therapy. This includes patients with very advanced liver disease, as well as patients with psychiatric diseases, autoimmune disorders, etc. For these patients, there is a very clear unmet medical need for new HCV treatment regimens.

The treatment of hepatitis C is a rapidly moving therapeutic area, with several new classes of direct-acting antivirals now in advanced stages of development. The European Medicines Agency is actively supporting the development of these new treatment options for patients through provision of scientific advice and drafting of guidance to developers of these medicines.

Sovaldi is the first representative of a new class of antivirals that act as inhibitors of an essential enzyme of HCV, the NS5B ribonucleic acid polymerase. This medicine provides the first interferon-free treatment option for chronic hepatitis C.

In clinical trials where sofosbuvir was used in combination with ribavirin alone, it has convincingly shown efficacy with a good safety profile. A high proportion of patients had no detectable virus in their blood 12 to 24 weeks after the end of the treatment and could therefore be considered to be cured of their hepatitis C virus infection.

Furthermore, when Sovaldi is used in combination with pegylated interferon as well as ribavirin, shortened treatment duration down to 12 weeks (compared to 24-48 weeks with the current standard of care) is possible and provides high efficacy. This is of value considering the side-effect profile of interferon.



New treatment option for HCV patients undergoing liver transplantation

HCV infection is the most common single cause of liver transplantation in the EU. However, patients who do undergo liver transplantation due to hepatitis C have a worse prognosis than patients who do so for other reasons, because recurrence of the virus in the graft is near-universal and often aggressive. For many of these patients, there are currently no approved treatment options that are likely to be effective.

In clinical trials, Sovaldi in combination with ribavirin has shown its capacity to prevent reinfection of the graft, and thus provides a treatment option for patients with HCV infection who are on the waiting list for liver transplantation.

Advice on compassionate use of sofosbuvir

During its October 2013 meeting, the CHMP gave an opinion on the conditions under which early access to sofosbuvir, in combination with other medicines, could be given in compassionate-use programmes, for patients with chronic hepatitis C infection before or after liver transplantation.

Such programmes, set up at the national level, are intended to give patients with a life-threatening, long-lasting or seriously disabling disease who have no available treatment options access to treatments that are still under development and that have not yet been authorised.

During its November meeting, the CHMP also provided an opinion on the use of a combination of sofosbuvir with the antiviral daclatasvir in certain patients with chronic hepatitis C virus (HCV) infection, in a compassionate-use programme.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing-authorisation applicant for Sovaldi is Gilead.
3. The CHMP advice on compassionate use of sofosbuvir in patients with chronic hepatitis C infection before or after liver transplantation is available here:
http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2013/10/WC500153144.pdf.
4. More information on the CHMP opinion on the use of the combination of sofosbuvir and daclatasvir in a compassionate-use programme is available in a separate press release.
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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