



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends approval of Daklinza in chronic hepatitis C

First-in-class medicine to offer new treatment option for patients

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended granting a marketing authorisation for Daklinza (daclatasvir) in combination with other medicines for the treatment of chronic (long-term) hepatitis C virus (HCV) infection in adults.

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 and is the most common single cause of liver transplantation in the EU.

The treatment paradigm of hepatitis C is currently rapidly shifting with the development of several new classes of direct-acting antivirals. Among these is Daklinza, which is the first representative of a new class of antivirals that block the action of NS5A, a protein which is essential for HCV to replicate.

Until very recently, the standard of care for hepatitis C included 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. One of the major benefits of the new antivirals is to provide an interferon-free treatment option for HCV infection.

There remains a public-health need to make such new treatment options available for patients where available interferon-free treatment regimens may have suboptimal effectiveness.

In November 2013, the CHMP gave an opinion on the conditions under which early access to daclatasvir, in combination with sofosbuvir, another direct-acting antiviral medicine, could be given in compassionate-use programmes.

The EMA is actively supporting the development of these new treatment options. The applicant for Daklinza, Bristol-Myers Squibb EEIG, received scientific advice from the CHMP during the development of this medicine. Daklinza was evaluated by accelerated assessment, a regulatory tool to help speed up patient access to new medicines where there is an unmet medical need.



Convincing efficacy with a good safety profile

The positive opinion granted by the CHMP for the marketing authorisation of Daklinza is supported by a pivotal trial in which the medicine was evaluated in HCV genotype-1, -2 and -3 infected patients, in combination with sofosbuvir with or without ribavirin. This study included a treatment arm with patients that previously failed on therapy with an NS3/4A inhibitor in combination with pegylated interferon and ribavirin. All such patients in the study reached a sustained virologic response, which is the goal of antiviral therapy for HCV. This trial is supported by a study of Daklinza in combination with pegylated interferon and ribavirin in patients with genotype 4 infection, and by several phase IIb trials of Daklinza with other combinations including with pegylated interferon and ribavirin.

The medicine showed convincing efficacy, in particular in combination with sofosbuvir, with an overall good safety profile.

The opinion adopted by the CHMP at its June 2014 meeting is an intermediary step on Daklinza'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 a marketing authorisation has been granted, decisions about price and reimbursement will then take place at the level of each Member State considering the potential role/use of Daklinza 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. More information on the CHMP's November 2013 recommendation on the use of daclatasvir in a compassionate use setting is available here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2013/11/news_detail_001971.jsp&mid=WC0b01ac058004d5c1
3. Sovaldi (sofosbuvir) was granted a marketing authorisation valid throughout the European Union on 16 January 2014. This medicine acts as an inhibitor of an essential enzyme of HCV, the NS5B ribonucleic acid polymerase. The marketing-authorisation holder for Sovaldi is Gilead. More information on Sovaldi can be found 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 the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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