21 July 2011
EMA/CHMP/554705/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Incivo

telaprevir

On 21 July 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Incivo, 375 mg, film-coated tablet intended for the treatment of chronic hepatitis C (CHC). The applicant for this medicinal product is Janssen-Cilag International N.V. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Incivo is telaprevir, a direct-acting antiviral, (ATC Code not yet assigned). Telaprevir is one of a new class of medicinal products for the treatment of chronic hepatitis that directly inhibit the replication of the hepatitis C virus in HCV-infected host cells.

The benefit of Incivo used in combination with ribavirin and peginterferon alfa is its ability to inhibit viral replication in infected host cells which can lead to the eradication of the virus, correlating to a cure of chronic hepatitis C. As compared to the current treatment with peginterferon alfa and ribavirin, the addition of telaprevir will significantly enhance the proportion of patients that could be cured of their hepatitis C. In some patients the gain of telaprevir will also be translated into a shorter treatment duration required for treatment response.

The most frequently reported adverse reactions were rash, anaemia, pruritus, nausea, and diarrhoea.

Telaprevir induces an incremental risk of rash including serious cutaneous reactions as compared to the combination of peginterferon alfa and ribavirin.

A pharmacovigilance plan for Incivo will be implemented as part of the marketing authorisation.

The approved indication is:

Incivo, in combination with peginterferon alfa and ribavirin, is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease (including cirrhosis):

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

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- who are treatment-naïve;
- who have previously been treated with interferon alfa (pegylated or non-pegylated) alone or in combination with ribavirin, including relapsers, partial responders and null responders (see sections 4.4 and 5.1)."

It is proposed that treatment with Incivo should be initiated and monitored by a physician experienced in the management of chronic hepatitis C.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Incivo and therefore recommends the granting of the marketing authorisation.