

Rottapharm | Madaus' Silibinin-C-2',3-dihydrogensuccinate, disodium salt (Legalon®SIL) Granted Orphan Medicinal Product Designation for the Prevention of Recurrent Hepatitis C in Liver Transplant Recipients by the European Commission

Monza, Italy - 19 January 2011 - Rottapharm | Madaus announced today that the European Commission (EC) has granted Orphan Medicinal Product Designation for its proprietary drug Legalon® SIL (silibinin-C-2',3-dihydrogensuccinate, disodium salt (SHS)), for the prevention of recurrent hepatitis C in liver transplant recipients¹.

Silibinin is a substance obtained by extraction from milk thistle fruits (Ph.Eur.) and is the main component of silymarin, the active ingredient of Rottapharm |Madaus' oral drug Legalon® which is approved for different indications within hepatic diseases and marketed worldwide. Silibinin-C-2',3-dihydrogensuccinate, disodium salt (SHS) is the silibinin form suitable for intravenous administration: it is the active ingredient of Legalon® SIL, a drug that is currently authorized and marketed since the mid-1980s for the treatment of acute Amanita phalloides mushroom intoxication. Legalon®SIL has been demonstrated to exert direct anti-viral effects against the hepatitis C virus (HCV) in patients resistant to standard therapy, and it is expected to be effective in the prevention of hepatitis C recurrence in liver transplant recipients.

The Company is currently investigating SHS in a number of ongoing studies, including Phase 2-3 clinical trials in orthotopic liver transplant patients.

The European orphan medicinal product designation is granted to medicines that may provide significant benefit to patients suffering from rare diseases identified as life-threatening or chronically debilitating, affecting no more than 5 in 10,000 persons in the European Union. The European Commission decision resulted from the positive opinion by the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

About recurrent hepatitis C in liver transplant recipients

The increasing burden of chronic HCV epidemic is reflected by increasing prevalence of end-stage liver diseases such as cirrhosis (liver scarring) and hepatocellular carcinoma. Liver transplantation (LT) is one of, if not "the most", formidable surgical procedure, and because of that, it is accompanied by frequent complications. While LT is the only therapeutic procedure in these end-stage liver diseases, it does not cure the HCV infection and re-infection of the liver allograft universally occurs shortly after transplantation. In LT recipients, differently from what observed in 20% of non-LT patients, spontaneous clearance of HCV infection never occurs and therefore these patients are all candidates to develop chronic HCV infection post-LT. At present, there is no satisfactory method of prevention that has been authorized in the European Union for the population at risk of developing the condition. The condition is chronically debilitating and life threatening due to the hepatic complications including cirrhosis and hepatocellular carcinoma.

About Rottapharm | Madaus

Established in 1961, Rottapharm|Madaus is a multinational pharmaceutical company primarily engaged in the research, development and global distribution of new pharmaceutical, nutraceuticals and personal care products in different therapeutic areas including gastroenterology, rheumatology, cardiology, gynaecology, paediatrics, dermatology, urology, oncology, bronchopneumology, psychiatry. The headquarters and main R&D site are located in Monza, Italy.

For more information: www.rottapharm.com

¹ European Medicines Agency Committee for Orphan Medicinal Products: Public summary of opinion on orphan designation, silibinin-C-2',3-dihydrogensuccinate, disodium salt for the prevention of recurrent hepatitis C in liver transplant recipients.
Silibinin-C-2',3-dihydrogensuccinate, disodium salt is now listed in the Community Register of designated Orphan Medicinal Products for Human Use under the number EU/3/10/828.

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