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EC approves expanded use of Daklinza (daclatasvir) for patients with chronic HCV and HIV co-infection

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Bristol-Myers Squibb today announced that the European Commission has approved the expanded use of Daklinza®▼ (daclatasvir), a first-in-class oral, once-a-day pill used in combination with other treatments as an option for adult patients with chronic hepatitis C virus (HCV) infection who are co-infected with HIV or who have had a prior liver transplant. This approval provides an important new oral treatment regimen for a complex set of patients and has been shown to cure the infection while being generally well tolerated.

Commenting on this milestone, Professor Geoffrey Dusheiko, Emeritus Professor of Medicine at the UCL Institute of Liver and Digestive Health, the Royal Free Hospital, London said:

> People with chronic hepatitis C who are co-infected with HIV or have had a liver transplant offer a unique challenge. Concurrent therapy must be carefully taken into consideration. However, the risks of disease progression in these groups of patients necessitates that they are a high priority for treatment. This approval now opens the door to a new treatment option that provides a high chance of curing the infection in a relatively short timeframe and is generally well tolerated.

HIV co-infected or post-liver transplant patients are complex patient groups. According to investigators from the UK Collaborative HIV Cohort (UK CHIC), nearly 9% of HIV-positive individuals in the UK - approximately 9,000 people - are also infected with HCV. HCV infection is also thought to progress more rapidly to liver damage in people with concurrent HIV infection.

It is also known that HCV infection is the cause of over 1 in 6 of all liver transplants in England and is the leading indication for liver transplantation worldwide. Without treatment, HCV infection of the new liver after transplant is inevitable. and is associated with rapid progression to cirrhosis, with up to 30% of transplanted patients developing cirrhosis within five years.

The ALLY-1 study evaluated the combination of daclatasvir and sofosbuvir with ribavirin regimen in 113 adult hepatitis C patients (treatment-naive or experienced) with either advanced cirrhosis or recurrent HCV post-liver transplant. The study's primary endpoints were reached, with 95% (n=39/41) of post-transplant genotype 1 patients and 82% (n=37/45) of genotype 1 patients with advanced cirrhosis being cured of their infection. In the advanced cirrhosis cohort, patients whose treatment was interrupted by liver transplantation could be given an additional 12 weeks of treatment immediately post-transplant. The combination of daclatasvir and sofosbuvir with ribavirin was generally well tolerated in both patient cohorts.

The ALLY-2 study evaluated the combination of daclatasvir and sofosbuvir administered for 12 weeks in 153 adults with chronic hepatitis C and HIV co-infection (treatment-naive or experienced). The study met the primary endpoint, with 96% (n=80/83) of treatment-naïve genotype 1 patients achieving being cured of their infection.

The overall safety profile of daclatasvir is based on data from 2215 patients with chronic HCV infection who received daclatasvir in a variety of all-oral regimens and with the current interferon-based standard of care. Across clinical studies, daclatasvir based regimens have been generally well tolerated with low rates of discontinuation across a range of patients.

Source:
http://www.bms.com/
