

AbbVie's hepatitis C drug Viekirax gets European approval

EUROPEAN COMMISSION GRANTS MARKETING AUTHORIZATIONS FOR ABBVIE'S VIEKIRAX® (OMBITASVIR/PARITAPREVR/RITONAVIR TABLETS) + EXVIERA® (DASABUVIR TABLETS) FOR THE TREATMENT OF CHRONIC HEPATITIS C

Jan 16, 2015

NORTH CHICAGO, Ill., Jan. 16, 2015 /PRNewswire/ -- AbbVie (NYSE: ABBV) announced that the European Commission has granted marketing authorizations for its all-oral, short-course, interferon-free treatment of VIEKIRAX® (ombitasvir/paritaprevir/ritonavir tablets) + EXVIERA® (dasabuvir tablets).^{1,2} The treatment has been approved with or without ribavirin (RBV) for patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including those with compensated liver cirrhosis, HIV-1 co-infection, patients on opioid substitution therapy and liver transplant recipients.^{1,2} Additionally, VIEKIRAX has been approved for use with RBV in genotype 4 (GT4) chronic hepatitis C patients.¹

"The approval of AbbVie's hepatitis C treatment in the European Union, following the recent approvals in the U.S. and Canada, offers patients across Europe a new and effective treatment to cure this serious disease," said Richard Gonzalez, chairman of the board and chief executive officer, AbbVie. "We are committed to working with local governments and healthcare systems to support broad access to VIEKIRAX + EXVIERA."

The approvals follow a review under accelerated assessment by the European Medicines Agency, designated to new medicines of major public health interest. Approximately nine million people in Europe are infected with chronic hepatitis C, a major cause of liver cancer and liver transplantation.⁴ Genotype 1 is the most prevalent form of hepatitis C in Europe, accounting for 60 percent of cases worldwide.⁵ In Europe, the most prevalent sub-genotype is 1b (47 percent).⁶ Genotype 4, most common in the Middle East, sub-Saharan Africa and Egypt, is becoming increasingly prevalent in several European countries, including Italy, France, Greece and Spain.⁷ AbbVie's treatment is now licensed for use in all 28 member countries of the European Union, as well as in the U.S., Canada, Switzerland, Iceland, Liechtenstein and Norway.

"Hepatitis C is a complex disease, with multiple genotypes and special patient populations that need to be considered when determining the right treatment for an individual patient," said Stefan Zeuzem, M.D., professor of medicine and chief of the department of medicine I, J.W. Goethe University Hospital, Frankfurt, Germany. "In clinical trials, AbbVie's treatment achieved high cure rates with low rates of discontinuation across a variety of patient populations, making it an important addition to the class of therapies that is changing the way hepatitis C is being treated."

Treating hepatitis C is complex because the virus mutates and replicates rapidly. VIEKIRAX + EXVIERA are the first products to be approved as a combination treatment of three direct-acting antivirals with distinct mechanisms of action and non-overlapping resistance profiles to target hepatitis C at multiple steps in the viral lifecycle.^{1,2}

"With the approval of VIEKIRAX + EXVIERA in the European Union, we are offering a treatment that achieved high cure rates for people living with GT1 and GT4 chronic hepatitis C," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "This is an important part of our ongoing commitment to advancing public health by applying innovative science to the development of promising medicines."