Europe Recommends Approval of AbbVie's '3D' Hep C Regimen

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A regulatory committee has recommended that the European Medicines Agency (EMA) approve AbbVie's "3D" regimen, with or without ribavirin, to treat genotypes 1 and 4 of hepatitis C virus (HCV), Reuters reports. The European Committee for Medicinal Products for Human Use (CHMP) made the recommendation based upon results from six Phase III studies, including SAPPHIRE-1 and -2, Pearl-2, -3 and -4, and TURQUOISE-2, which together included more than 2,300 participants with genotype 1 in more than 25 countries.

Additionally, CHMP reviewed results form the Phase II PEARL-1 study of genotype 4 participants without cirrhosis, as well as preliminary findings from the TURQUOISE-1 study of people coinfected with HIV and genotype 1 of HCV, and from the CORAL-1 study of liver transplantees who had recurrent genotype 1 of hep C and who were receiving their first treatment for the virus after transplantation.

The 3D regimen consists of two pills: The coformulated, once-daily tablet called Viekirax, which includes the NS5A inhibitor ombitasvir, the protease inhibitor paritaprevir, and Norvir (ritonavir), plus a twice-daily tablet of the non-nucleoside polymerase inhibitor Exviera (dasabuvir).

"The CHMP positive opinions mark an important milestone in our HCV development program and recognize the potential our treatment brings to people in Europe living with this chronic condition," Michael Severino, MD, executive vice president of research and development and chief scientific officer at AbbVie, said in a press release. "Our treatment has been developed with the goal of achieving high cure rates in a broad range of genotype 1 patients with low rates of discontinuation and relapse."

The EMA is expected to issue a decision on the regimen during the first quarter of 2015.

To read the AbbVie press release, click here.

To read the Reuters story, click here.

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