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FDA: AbbVie Hepatitis therapy is a 'breakthrough'

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Singapore: AbbVie's investigational direct-acting antiviral (DAA) combination with and without ribavirin for the treatment of genotype (GT1) hepatitis C virus (HCV) infection has been designated as a Breakthrough Therapy by the US FDA.

The designation is based, in part, on positive data from AbbVie's clinical development program, including the phase IIb clinical trial M11-652, known as 'Aviator'.

According to the FDA, the Breakthrough Therapy designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy designation includes preliminary clinical evidence demonstrating that a drug may have substantial improvement on at least one clinically significant endpoint compared to available therapy.

A Breakthrough Therapy designation conveys all of the fast track program features, as well as more intensive FDA guidance on an efficient drug development program.

Dr John M Leonard, senior VP and chief scientific officer, AbbVie, said that, "AbbVie is pleased that the FDA has granted Breakthrough Therapy designation to our 3-DAA combination with and without ribavirin. We feel it reflects the potential of this regimen to be important in the treatment of HCV. Our HCV program is one part of our advancing pipeline which is focused on delivering innovative therapies to address pressing areas of unmet clinical need."