Telaprevir, Boceprevir for Hep C Approaching FDA Finish Line

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Two experimental hepatitis C virus protease inhibitors are scheduled to undergo approval review by the U.S. Food and Drug Administration's Antiviral Drugs Advisory Committee at the end of April, according to a report from Dow Jones Newswires.

Approval applications for Merck's boceprevir will be reviewed by the committee April 27, whereas documentation supporting Vertex's telaprevir will be reviewed April 28. Upon completing its review of each new drug application (NDA) and hearing from researchers, hepatitis C community advocates and the drugs' sponsors, the committee will recommend to the FDA whether or not to approve the drugs.

Both drugs are expected to come to the market at similar times and to be widely used, according to the Dow Jones report. The report adds that Merck was granted an expedited six-month review by the FDA in 2011; Vertex is expecting an approval decision by May 23.

According to clinical trial data reported by researchers thus far, both drugs substantially increase the likelihood of sustained virologic responses (SVRs)—defined as HCV viral loads that remain undetectable after treatment is discontinued—in both patients starting hepatitis treatment for the first time and those who did not respond favorably to treatment in the past.

Both telaprevir and boceprevir must be combined with pegylated interferon and ribavirin for the first three months of treatment.

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