Vertex Hep C Protease Inhibitor Receives Approval Recommendation

April 28, 2011

The Antiviral Drugs Advisory Committee (ADAC) of the U.S. Food and Drug Administration (FDA) voted 18 to 0 to recommend approval of telaprevir, Vertex Pharmaceuticals' experimental hepatitis C virus (HCV) protease inhibitor. The panel of independent experts met Thursday, April 28, to review the company's New Drug Application requesting approval for the drug.

The expert panel's nod of approval follows a similar unamimous recommendation for Merck's HCV protease inhibitor Victrelis (boceprevir) on Wednesday, April 27.

Telaprevir, with the ADAC panel's recommendation, now goes to the FDA for final consideration as a treatment for HCV genotype 1 infection in combination with current standard therapy, notably pegylated interferon and ribavirin. The agency will consider the drug's established safety and efficacy for those who have not yet been treated for HCV and for those who have been treated previously but were not cured with currently available medications.

The advisory committee panel reviewed the results from three pivotal clinical trials—ADVANCE, ILLUMINATE and REALIZE—which evaluated telaprevir in combination with pegylated interferon and ribavirin in people who were not treated previously and in the three major subgroups of patients who did not respond favorably to earlier treatment: Relapsers, partial responders and null responders.

Vertex anticipates a decision for the FDA by May 23.