Hep C Treatment Telaprevir Gets Fast-Tracked FDA Review

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Vertex Pharmaceuticals announced on January 20 that the U.S. Food and Drug Administration (FDA) has agreed to expedite its approval review of the experimental hepatitis C protease inhibitor telaprevir. The agency has until May 23—six months from the original New Drug Application (NDA) filing date of November 23—to complete its review.

Vertex also announced the completion of a New Drug Submission (NDS) to the Therapeutic Product Directorate (TPD) of Health Canada seeking approval for telaprevir in Canada, where it was also granted Priority Review.

The U.S. NDA and Canadian NDS are supported by results from three Phase III studies evaluating the protease inhibitor in people chronically infected with genotype 1 hepatitis C virus (HCV) who were new to treatment as well as those who were treated before but did not achieve a sustained virologic response (SVR, or viral cure).

All Phase III studies, in which telaprevir was started immediately in combination with standard HCV treatment (pegylated interferon plus ribavirin) for the first 12 weeks of treatment, met their primary objectives.

In people with hepatitis C who were new to treatment, up to 75 percent achieved an SVR with telaprevir-based combination therapy, compared with 44 percent of people who received pegylated interferon and ribavirin alone. What's more, a majority of patients treated with telaprevir in the treatment-naive studies (ADVANCE and ILLUMINATE) were eligible to reduce their treatment time by half—from 48 to 24 weeks.

Among those who had not achieved an SVR with an earlier course of treatment, SVRs were significantly more likely to be documented upon retreatment with the addition of telaprevir, compared with those retreated with pegylated interferon and ribavirin alone.

Standard review in the United States takes about 10 months. Priority Review shortens the review time to six months. And in Canada, where standard review can take at least 18 months, Priority Review results in an approval decision from TPD within six to nine months.

Vertex is developing telaprevir in collaboration with Tibotec Pharmaceuticals and Mitsubishi Tanabe Pharma. Vertex has rights to commercialize telaprevir in North America, and Tibotec has rights in Europe, South America, Australia, the Middle East and certain other countries. Mitsubishi Tanabe Pharma has rights to commercialize telaprevir in Japan and certain Far East countries.

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