Hep C Protease Inhibitor Telaprevir Now Under Review for FDA Approval

December 2, 2010

Vertex Pharmaceuticals announced on November 23 that it has completed the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) seeking approval for telaprevir, the company's experimental treatment for people with hepatitis C. The NDA submission is 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).

The NDA includes a request for Priority Review, which would reduce the FDA's review time from 10 months to six months.

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-naïve 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 a prior 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.

"In our trials, starting patients with 12 weeks of telaprevir-based combination therapy significantly improved viral cure rates compared to treatment with currently approved medicines, even in groups of people considered the most difficult to treat," said Peter Mueller, PhD, chief scientific officer and executive vice president of Global Research and Development at Vertex. "We're also encouraged by telaprevir data that showed most patients new to therapy were able to achieve high viral cure rates and reduce their total treatment time by half."

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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