Vertex’s hepattitis drug wins FDA approval

By Herald Staff
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The U.S. Food and Drug Administration today approved Vertex’s Incivek, also known as telaprevir, a potential blockbuster drug to treat chronic hepatitis C infection.

Developed by Cambridge-based Vertex Pharmaceuticals, the drug is used for patients who have either not received interferon drug therapy for their infection or who have not responded adequately to other treatments.

The safety and effectiveness of Incivek was evaluated in three Phase 3 clinical trials with about 2,250 adult patients.

“With the approval of Incivek, there are now two important new treatment options for hepatitis C that offer a greater chance at a cure for some patients with this serious condition,” said Dr. Edward Cox, director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research, in a statement, referring to a competing treatment by Merck. “The availability of new therapies that significantly increase responses while potentially decreasing the overall duration of treatment is a major step forward in the battle against chronic hepatitis C infection.”

The U.S. Centers for Disease Control and Prevention reports that about 3.2 million people in the United States have chronic hepatitis C infection, a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure.

Most people with hepatitis have no symptoms of the disease until liver damage occurs, which may take several years.

Vertex has said that it would start construction of a 1.2 million square foot office and lab complex on Fan Pier in Boston once the drug was approved.