FDA Gives Hep C Drug Incivek ’Black Box’ Warning for Causing Fatal Skin Reactions

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Vertex Pharmaceuticals’ hepatitis C antiviral Incivek (telaprevir) has caused two deaths due to serious skin reactions, The Boston Globe reports. Consequently, the U.S. Food and Drug Administration (FDA) has given the drug its most severe “black box” warning, alerting consumers to both fatal and nonfatal serious skin reactions.

One of two FDA-approved protease inhibitors available for use in triple combination therapy with interferon and ribavirin to cure hepatitis C virus (HCV), Incivek caused skin reactions in less than 1 percent of those taking the antiviral in Phase III clinical trials. Some of those study participants were subsequently hospitalized, but there were no fatalities. This is the first report of deaths from the drug. Vertex urges anyone who has a skin reaction to stop treatment immediately, as the two who have died continued therapy after identifying the reaction.

To read the Boston Globe report, click here.

To read the Vertex statement, click here.

Editor’s Note: A previous version of this article stated Vertex had not yet disclosed the number of deaths due to Incivek. The article has since been updated to reflect the number of fatalities is two.

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