

US approves second new hepatitis C drug

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The US Food and Drug Administration on Monday approved Incivek to treat hepatitis C when taken along with the current two-drug regimen, marking the second such drug approval this month.

"The sustained virologic response for patients treated with Incivek across all studies, and across all patient groups, was between 20 and 45 percent higher than current standard of care," the FDA said.

Incivek is a pill that should be taken three times a day with food, and is added to therapy made up of peginterferon alfa and ribavirin.

In mid-May, the US regulatory agency approved a Merck-made pharmaceutical known as Victrelis. Both have been shown to boost cure rates when added to the present regimen, which helps fewer than 50 percent of people with the liver disease.

The existing two-drug treatment of pegylated interferon and ribavirin for genotype 1 chronic <u>hepatitis</u> C was approved by US regulators in 1998.

"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 Edward Cox, director of the office of antimicrobial products in FDA's Center for Drug Evaluation and Research.

"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."

Incivek, or telaprevir, is marketed by the Massachusetts-based <u>Vertex</u> <u>Pharmaceuticals</u>.

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