FDA to review re-submitted Bristol-Myers hepatitis C drug

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(Reuters) - U.S. regulators have accepted Bristol-Myers Squibb Co's re-submitted marketing application for an experimental hepatitis C treatment after the drugmaker was forced last year to withdraw its initial request.

Bristol-Myers on Thursday said the U.S. Food and Drug Administration will review daclatasvir, its so-called NS5A inhibitor, for use in combination with Gilead Sciences Inc's potent and widely used Sovaldi treatment. It said the FDA is expected to make its decision within six months.

Bristol-Myers originally had sought FDA permission to market daclatasvir in combination with another Bristol drug, asunaprevir. But it abandoned that application due to potential competition from more potent drugs, leaving the FDA without data to gauge the effectiveness of daclatasvir as part of a combination regimen.

Bristol-Myers then went back to the drawing board, collecting data from a separate large trial in which daclatasvir was tested with Sovaldi in patients with a different and less-common strain of hepatitis C, called genotype 3.

In that late-stage trial, 90 percent of previously untreated patients had no trace of the virus after 12 weeks of treatment.

Daclatasvir is already approved in Europe, Brazil and Japan as part of a combination therapy.