FDA Requests More Data on BMS's Hep C Drug Daclatasvir

December 1, 2014

The U.S. Food and Drug Administration has requested additional data from Bristol-Myers Squibb about the hepatitis C virus (HCV) drug daclatasvir's use in combination with other direct-acting antivirals (DAAs).

In April, BMS submitted a new drug application for approval of the NS5A complex inhibitor daclatasvir with the NS3/4A protease inhibitor asunaprevir. But in October BMS withdrew its application for asunaprevir, apparently owing to the drug's feeble performance when compared with other drugs pending approval.

The FDA's Complete Response Letter (CRL) to the daclatasvir portion of the application has now opened discussions with BMS about what sort of data is needed to support the safety and efficacy of daclatasvir when given in combination with other DAAs. BMS believes a refashioned application for daclatasvir can be accomplished from data from completed and ongoing studies of the drug.

The FDA did not express any concerns about daclatasvir's safety in the CRL.

"Despite the recent advances in the treatment of hepatitis C there remain significant areas of unmet high need in this disease area," said Francis Cuss, executive vice president and chief scientific officer of research and development at BMS. "Our commitment remains to make daclatasvir-based regimens available to help these difficult-to-treat patients achieve cure, and we will continue to collaborate with the FDA to bring daclatasvir to patients in the U.S. as quickly as possible."

To read the BMS press release, click here.

© 2026 Smart + Strong All Rights Reserved.

http://beta.docker.hepmag.com/article/daclatasvir-FDA-26505-1205626746