FDA Grants ‘Priority Review’ to AbbVie’s ‘3D’ Hep C Regimen

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The U.S. Food and Drug Administration has granted AbbVie’s so-called ‘3D’ hepatitis C virus (HCV) treatment “priority review” status. The combination therapy, which AbbVie submitted to the FDA for approval April 21, received FDA designation as a “breakthrough therapy” in May.

The 3D regimen consists of a fixed-dose combination of the protease inhibitor ABT-450 and ritonavir co-formulated with the NS5A inhibitor ombitasvir (ABT-267), as well as the non-nucleoside polymerase inhibitor dasabuvir (ABT-333), with or without ribavirin.

The FDA grants priority review to drugs that may offer a major advance in treating a condition. By law, the FDA review will begin about 60 days after the new drug application with a goal of completing the process within six months. Thus, the review should start at the end of June and wind up by the end of December.

Gilead Sciences’ combination therapy of Sovaldi (sofosbuvir) and ledipasvir has also received priority review, and a decision is expected October 10.

To read the AbbVie press release, click here.

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http://beta.docker.hepmag.com/article/AbbVie-3D-priority-25781-1161722573