FDA to Rescind ’Breakthrough’ Status for BMS Hep C Drug Daclatasvir

February 23, 2015

The U.S. Food and Drug Administration (FDA) has informed Bristol-Myers Squibb (BMS) of its intention to rescind the “breakthrough” designation for the company’s investigatory hepatitis C virus (HCV) therapy daclatasvir, FierceBiotech reports. The agency recently informed Merck that it also plans to rescind the breakthrough designation for that company’s fixed-dose tablet of grazoprevir and elbasvir.

The FDA grants breakthrough therapy designation to investigatory drugs if research suggests they offer a significant improvement on existing therapies. The nod allows for an expedited review process. Unfortunately for BMS and Merck, Gilead and AbbVie have beat them to the punch with the recent approvals of Harvoni (ledipasvir/sofosbuvir) and Viekira Pak (ombitasvir/paritaprevir/ritonavir; dasabuvir), respectively. The FDA’s recent shift with regards to daclatasvir and grazoprevir/elbasvir implies that it does not anticipate that people with hepatitis C will reap greater benefits from these drugs than existing HCV therapies. (This says nothing, however, of how the approval of BMS’s and Merck’s medications may affect the overall pricing of hep C therapies.)

BMS experienced a previous FDA-related fumble in October when it withdrew its application for approval of daclatasvir in combination with asunaprevir, taking the disappointing latter drug out of the running entirely. BMS intends to resubmit its application for daclatasvir to the FDA in the near future.

To read the FierceBiotech story, click here.

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