AbbVie Files for FDA Approval of ’3D’ Hepatitis C Regimen

April 22, 2014

On April 22, AbbVie submitted a new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for its so-called “3D” combination regimen of antivirals to treat adults with genotype 1 of hepatitis C virus (HCV). Supporting the application are six Phase III studies of the treatment in more than 2,300 people around the world—the largest such research program to date in the fast-evolving and highly competitive field of hep C research and development.

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

In May, the FDA gave the regimen a Breakthrough Therapy Designation, giving it an expedited review process because it may substantially improve upon currently available treatment options.

“This NDA submission is a significant advancement for AbbVie’s HCV development program,” Scott Brun, MD, vice president of pharmaceutical development at AbbVie, said in a release. “Based on the robust data that have been generated in our international Phase III HCV program, we believe our all-oral, interferon-free regimen holds the potential to be a promising new therapy for patients living with this chronic infection.”

With this application, AbbVie raises the stakes in the race to develop blockbuster therapies to treat hep C and tap into potential billions of dollars in sales. On February 10, Gilead filed for approval of the once-daily fixed-dose combination tablet of ledipasvir and the already-approved Sovaldi (sofosbuvir) to treat genotype 1 of hep C. Word on the FDA’s decision about that combination therapy is expected October 10. On April 7, Bristol-Myers Squibb filed for approval of daclatasvir and asunaprevir in combination to treat genotype 1b and for daclatasvir to be used with other hep C antivirals to treat various genotypes.

Thus, the year’s end is likely to yield highly dramatic changes in the treatment options for people living with the virus, as well as a potential price war as pharmaceutical companies seek to curry the favor of insurers who have suffered sticker shock over Sovaldi’s thousand-dollar-a-day price.

AbbVie also plans to submit an application for the regimen to the European Union in May.

To read the press release, click here.

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