Gilead Files for FDA Approval of Fixed-Dose Sovaldi/Ledipasvir

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Gilead Sciences has submitted a new drug application to the U.S. Food and Drug Administration for a once-daily fixed-dose combination pill of the NS5A inhibitor ledipasvir and the already-approved analog polymerase inhibitor Sovaldi (sofosbuvir) (LDV/SOF) for the treatment of people with genotype 1 of hepatitis C virus (HCV). The application seeks approval for eight- or 12-week treatment regimens, depending on past treatment experience and whether the person undergoing treatment has cirrhosis.

The FDA has already granted the combination pill a “Breakthrough Therapy” status because it may offer a significant advance over currently available therapies. The treatment notably dispenses of the weekly injections of interferon, which can cause flu-like side effects. Long a mainstay of hep C treatment, interferon has begun to fall out of use with the introduction of Sovaldi in December 2013, but not for all people with genotype 1, which is the most common in the United States. Trials of the ledipasvir/Sovaldi pill have boasted near-perfect cure rates.

“Today’s filing brings us one step closer to our goal of offering all patients with hepatitis C a simple, safe and highly effective all-oral treatment regimen,” Norbert Bischofberger, PhD, executive vice president of research and development and chief scientific officer at Gilead, said in a release. “Based on the data from the Phase III ION studies, the LDV/SOF combination may have the potential to cure HCV in genotype 1 patients in as little as eight weeks and without the need for interferon injections or ribavirin.”

Gilead has submitted the results from three major Phase III studies in its application: ION-1, ION-2 and ION-3. Between these three trials, almost 2,000 people with genotype 1 of hepatitis C were randomized to receive the combination pill, with or without ribavirin, for 8, 12 or 24 weeks. The pool of participants in the studies included those who were treatment naive and those who had failed previous attempts at a cure. People with compensated cirrhosis were also included.

To read a copy of the release, click here.

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