

AbbVie's new hepatitis C treatment gets approval in EU

January 19 2015, by Linda A. Johnson

Drugmaker AbbVie Inc. said Monday that its new, all-pill hepatitis C combo treatment has been approved for patients in the 28 European Union member countries.

The company said the European Commission granted marketing authorization for the combination of Viekirax and Exviera. Viekirax itself is a combination pill containing antiviral drugs ombitasvir, paritaprevir and ritonavir; Exviera is a single pill containing dasabuvir.

It's already approved in EU nonmembers Switzerland, Norway, Iceland and Liechtenstein, plus Canada and the U.S. In some countries, Viekirax and Exviera are sold separately, while in others, including the United States, they are packaged together under the name Viekira Pak.

They're part of a new generation of hepatitis C treatments that are extremely expensive but don't require any injections, have fewer side effects and cure nearly all patients in as little as eight weeks. Rival Gilead Sciences Inc. has two such drugs, Sovaldi and a slightly newer combo pill called Harvoni.

Older treatments require weekly injections of interferon—genetically engineered versions of immune system proteins—which cause flu-like side effects many patients can't tolerate and can cause or worsen psychiatric, immune system, cardiac and infectious disorders. Those medicines must be taken for as long as a year and still barely cure half of patients with the liver-damaging disease.

The newer medicines, particularly Sovaldi, have become targets for critics of the sky-high prices drugmakers are demanding for new medicines. Sovaldi's list price is \$84,000 for a course of treatment, Harvoni's is about \$94,000 and Viekira Pak's is \$83,300.

Major insurers have been demanding sizable discounts to cover the medicines, while some state Medicaid programs have been limiting approvals to the very sickest patients. At least one health plan has sued Gilead, alleging "unjust enrichment" due to Sovaldi's price.

In patient studies, AbbVie's Viekirax and Exviera cured 95 percent to 100 percent of patients with the genotype 1 subset of hepatitis C, the most common in Europe and the U.S.

The EU approval is for patients with genotype 1 and, for patients who have genotype 4, combining those pills with the drug ribavirin.

Roughly 3.2 million Americans are infected with hepatitis C, which generally doesn't cause noticeable symptoms until the liver is damaged. Without proper treatment, up to 30 percent eventually will develop cirrhosis, or scarring of the liver tissue. The virus can cause liver failure and liver cancer, resulting in the need for a liver transplant.

AbbVie, based in North Chicago, Illinois, sells Humira for rheumatoid arthritis and other immune disorders and AndroGel, a testosterone replacement gel.

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