

REPORT ON ZEPATIER DRUG

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Merck & Co. Inc. is a well-known American drug developer and manufacturer. The company has produced multiple pharmaceutical products sold successfully worldwide. Among these products is Zepatier, a hepatitis drug developed by Merck and approved by the U.S. Food and Drug Administration on 28th January 2016¹. The drug is composed of two components, elbasvir and grazoprevir, can be prescribed with or without ribavirin, and is used to treat adult patients suffering from hepatitis C genotype 1 and 4 within a 12-week treatment course². Zepatier contains 50 milligrams of an NS5A inhibitor and 100 milligrams of a protease inhibitor, grazoprevir. The product was also approved for the treatment of chronic hepatitis C virus in patients with renal disease receiving hemodialysis³.

Although this drug has been of benefit to the United States, its development was not a simple task for Merck. One of the challenges that the company faced was from mutations contained in hepatitis C virus, which led to resistance to the treatment in some patients with genotype 1 infection. The drug producer recommended to resolve the issue by resistance polymorphism testing before administering the treatment. A brief list of other obstacles Merck had to overcome shows the process complexity and importance for the entire health care system:

- Complications seeking regulatory approval due to varying legislative requirements within the USA and abroad;
- Technological advancement and new generic and similar products developed by competitors;

¹. "FDA Approves Zepatier For Treatment Of Chronic Hepatitis C Genotypes 1 And 4". 2016.

². Ibid.

³. "Merck's HCV Doublet Wins FDA Approval; Prepares To Take On Gilead's Blockbusters". 2016

- Difficulty establishing a competitive price for the treatment;
- Difficulty predicting future market conditions accurately;
- Manufacturing delays;
- International economy instability.

Notwithstanding the fact that Zepatier has been helpful to adult patients with hepatitis C virus, it has several side effects that the health care practitioners must carefully consider before prescribing the treatment and in the process thereof. The drug can cause the symptoms associated with liver malfunction, which prompts extensive liver-related blood tests. Should any of such tests detect liver impairment of moderate to severe complexity, the treatment with Zepatier is prohibited⁴. Other side effects include loss of appetite, nausea and vomiting, fatigue, yellowing of the skin or eyes, and changes in stool color. The side effects associated with Zepatier depend on whether the medication is used with or without ribavirin. In treatment without ribavirin, the following are common adverse effects: fatigue, nausea, headache, insomnia, and diarrhea. When used in combination with ribavirin, common adverse reactions are as follows: anemia, severe headache, fatigue, feeling irritable, stomach pain, shortness of breath, joint pain, and itching.

Additionally, there are some considerations either to be resolved or taken into account when planning the treatment. Firstly, Zepatier is counter-indicated to women who are pregnant and men whose sexual partners are pregnant⁵. Secondly, though being proven effective in adults, it is not clear whether the drug can improve the condition of children below 18 years of age and

⁴ "FDA Approves Zepatier For Treatment Of Chronic Hepatitis C Genotypes 1 And 4". 2016.

⁵ Ibid.

people with liver transplant or those waiting for a liver transplant and undergoing corresponding procedures.

In conclusion, Merck's Zepatier shows great competitive potential being in the same price range with other manufacturers of similar-effect medications and looking to obtain approval for European market. When granted, such authorization will enable the company to provide hepatitis C treatment to patients with genotype 1, 3, 4 or 6 viruses. It is not in Merck's plans to stand still and collect revenues. Curing hepatitis being one of its major goals, the company already plans to develop new HCV drugs considering that the global patents for grazoprevir and elbasvir expire in 2029 and 2030 respectively. Based on the data reported above and the history of the company's success, it can be said with certainty that Merck's ambitions are most likely to be fulfilled.

Bibliography

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