Report Outline

I. Introduction

The report focuses on Zepatier, a drug developed by Merck & Co. Inc. and approved by the U.S. Food and Drug Administration in 2016. The product is used to treat patients suffering from chronic hepatitis C virus (HCV) genotype 1 and 4 in adult patients. Zepatier can also be administered to patients undergoing hemodialysis. The treatment duration is 12-weeks.

II. Challenges faced by the manufacturer in the process of Zepatier development and approval.

1. Resistance to treatment due to HCV mutations in patients with genotype 1 virus.
2. Legal obstacles caused by varying U.S. and international legislative requirements.
3. Competitors' activities and achievements in the field of technology and product development.
4. Difficulties associated with market conditions and pricing policy.

III. Side effects and counterindications yet to be resolved.

1. Common adverse effects when the drug is taken with or without ribavirin:

a) nausea;

b) fatigue;

c) headache.

Other side effects might include yellowing of skin and eyes, change of stool color, insomnia, diarrhea, stomach pain, etc. Some adverse reactions depend on whether the

drug is taken together with ribavirin or without it. Additionally, liver malfunction can occur in week 8 of treatment, that is why liver-related blood tests must be carried out prior to and during the treatment.

2. Zepatier is counterindicated in cases listed below:

a) moderate to severe liver impairment;

b) pregnancy;

c) pregnant partners in case of male patients.

3. The drug's efficacy in patients under 18 has not been established.

III. Conclusion

Zepatier has been proven effective in treating patients with hepatitis C genotype 1 and 4 and even in patients undergoing hemodialysis. Despite facing multiple challenges during the drug development and approval, Merck & Co. Inc. is looking to obtain approval for European market, which will enable the company to provide hepatitis C treatment to patients with genotype 1, 3, 4 or 6 viruses.