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Short Communication

VEMLIDY (TENOFIVIR ALAFENAMIDE) FOR CHRONIC HEPATITIS B

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ABSTRACT

Hepatitis was once viewed as a rampant and incurable disease but within recent years therapies have been released that offer hope and the improvement in quality of life through symptoms control. The purpose of this manuscript is to discuss the use of VEMLIDY as a new treatment for hepatitis B and examine its use among the current therapies that are on the market. VEMLIDY offers another therapeutic option for patients currently diagnosed with this Hepatitis B and for those who may have failed therapy with other agents.

Keywords: Hepatitis B, Chronic infection, Antiviral medications, VEMLIDY.

INTRODUCTION

Hepatitis B is considered to be an infectious disease that is caused by the hepatitis B virus (HBV) and this has the ability to affect the liver causing either acute or chronic type infections. The acute form of hepatitis B is one that is newly acquired and symptoms can present about 1 to 4 months after exposure to the virus. Chronic hepatitis can last longer than 6 months and will never go away completely. It is reported that about 1.25 million people in the United States have chronic infection of hepatitis B and between 20 and 30% of adult Americans with chronic hepatitis B generally become infected during their childhood. It is reported that over 686,000 people die each year from complications of hepatitis B such as cirrhosis and liver cancer even though 30% of those that are infected may not show any signs of symptoms (Hepatitis Statistics, 2011 and WHO, 2016). The classic signs and symptoms of hepatitis B infection can include abdominal pain, dark urine, fever, joint pain, or loss of appetite to name a few (Disease and Conditions: Hepatitis B, 2014).

HBV is a blood-borne virus and it can be transmitted from one individual to another through blood or fluid that has been contaminated with blood (Nettleman, 2016). Another notable route of transmission is from an infected mother to a newborn. The direct contact

with blood which can occur through the use of dirty needles can also be a contributing factor to contracting the infection. Individuals that have been identified as being at risk for hepatitis B include men or women with multiple sex partners that do not use protection, men who have sex with men, individuals with HIV or hepatitis C, individuals who inject drugs with shared needles, and those who undergo dialysis for kidney disease (Disease and Conditions: Hepatitis B, 2014 and Nettleman, 2016).

The treatment of hepatitis B can be based on whether it is considered to be acute or chronic. The development of acute hepatitis B can be transient and resolve on its own. However, if an individual has chronic hepatitis B they will require more intensive treatment which generally starts when blood test confirm that liver functions are declining and the amount of replicating HBV is rising. Antiviral medications are typically used to help reduce the virus' ability to reproduce and allow the liver to heal (Brooks, 2016)

Examples of agents that have historically been used to treat hepatitis B include Pegylated interferon alfa-2b (Pegasys) and Nucleoside/nucleotide analogues (NAs). In November 2016, the Food and Drug Administration approved another agent,

VEMLIDY (tenofovir alafenamide) developed by Gilead Sciences, to provide another option on the market to treat chronic hepatitis B virus infection (Brooks, 2016). VEMLIDY is a novel prodrug of tenofovir (Viread) that has a similar efficacy to tenofovir but at a dose that is less than one tenth (Brooks, 2016). Its approval was based on a 48 week data that came from two international phase 3 studies in which patients were randomized to either VEMLIDY or Viread. With both studies VEMLIDY was shown to be noninferior to Viread (Brooks, 2016).

Indication

VEMLIDY (tenofovir alafenamide) is a once-daily hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor that is indicated for the treatment of adults with chronic HBV infection with compensated liver disease.

Mechanism of Action

VEMLIDY works by inhibiting reverse transcriptase and incorporates into viral DNA, resulting in DNA chain termination (<https://www.drugs.com/VEMLIDY.html> and VEMLIDY™).

Dosing and Administration

For the treatment of chronic hepatitis B infection in patients with compensated liver disease, VEMLIDY is delivered as a 25 mg tablet that is taken once daily with food. Prior to initiation, a test for HIV antibody should be performed (<https://www.drugs.com/VEMLIDY.html> and VEMLIDY™). VEMLIDY should be avoided

in patients with a creatinine clearance of less than 15 ml/min and contraindicated in those with a hypersensitivity to VEMLIDY or any component (VEMLIDY™, 2017).

Warning and Precautions

Caution is to be exercised in those with renal disease, concurrent or recent nephrotoxic agent use, hepatic disease risk, or obesity (VEMLIDY™, 2017). VEMLIDY also carries a boxed warning that indicates the risk of lactic acidosis/severe hepatomegaly with steatosis and posttreatment severe acute exacerbation of hepatitis B (Brooks, 2016; VEMLIDY™, 2017 and VEMLIDY, 2017).

There is currently no human data available on the effects of VEMLIDY and breastfeeding and milk production, so caution should be advised.

Adverse Reactions

During clinical trials, the most commonly reported adverse reactions included headache, abdominal pain, fatigue, cough, nausea, and back pain (VEMLIDY Medication Guide, 2017). The more serious reactions include lactic acidosis, hepatomegaly with steatosis, hepatotoxicity, nephrotoxicity, HBV exacerbation, and pancreatitis (VEMLIDY, 2017 and VEMLIDY Medication Guide, 2017).

Drug Interactions

The major drug interactions associated VEMLIDY include p-gp substrate and its absorption can potentially be altered by Orlistat (VEMLIDY Medication Guide, 2017).

Pharmacokinetics

VEMLIDY is a prodrug that is converted to tenofovir. It comes as a 25 mg tablet that undergo CYP450 metabolism; 3A substrate. It is largely excreted through the feces at 31.7% ((VEMLIDY, 2017 and VEMLIDY Medication Guide, 2017).

Clinical Pearls

- There is the possible risk of low birth weight with the use of VEMLIDY based on limited human data.
- The tablet should be taken with food.
- The use VEMLIDY should be avoided in patients with creatinine clearance less than 15 ml/min.
- If a patient experiences an adverse reaction that is thought to be due to VEMLIDY, their physician should be contacted.

- Patients should be informed of informing their healthcare providers about all medications they are on including herbal, supplements, nutraceuticals, etc. given the risk of nephrotoxicity, lactic acidosis, and pancreatitis
- Patients should be informed about not changing their dose or stop taking VEMLIDY without first talking with your healthcare provider.

VEMLIDY offers another treatment option for patients with Hepatitis B, and this addition offers the opportunity for improvement of symptoms and long-term management. The potential for disease control is of the utmost importance for any patients diagnosed with Hepatitis B and the release of VEMLIDY provides this opportunity for proper management.

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