An estimated 230,000 Vietnam era veterans are infected with HCV, where it was spread by the military through vaccinations and battlefield blood transfusions.

(Newswire.net -- April 7, 2017) -- Interferon-based antiviral regimens used to treat hepatitis C virus (HCV) infection until 2011 had low response rates, long duration, multiple side effects and several contraindications to treatment. These factors limited the number of HCV-infected patients who received treatment and even more so the number who achieved eradication of HCV, known as ‘sustained virological response’ (SVR). Only an estimated 5–6% of all HCV-infected persons in the United States attained SVR in the interferon era.

Highly effective direct antiviral agents (DAAs) for hepatitis C virus (HCV) were introduced starting in late 2014. These DAAs have SVR response rates that exceed 90%. However, their utilization has been limited by high cost and low access to care.[i]

The two biggest providers of DAAs are Gilead Sciences Inc. and Merck & Co, Inc. who market Harvoni® and Zepatier® respectively.

What is Hep C?

Hepatitis C, or HCV, is a disease caused by a virus that infects the liver. The other common hepatitis viruses are A and B, which differ somewhat from HCV in the way they are spread and treated.[ii]

According to the Centers for Disease Control (CDC), there are from 2.7 million to 3.9 million people in the United States who have chronic Hepatitis C infections.[iii]

WHAT CAUSES HEP C?

HVC is spread through blood-to-blood contact. HCV was not screened for in the public blood supply before the mid 1980s. Because HCV infection usually produces no symptoms or very mild symptoms during the early stages, many people don’t know they have it until liver damage shows up during routine medical tests. Some people who get HCV have it for a short time (up to six months) and then get better on their own (acute Hepatitis C). But most people (about 75% – 85%) will go on to develop chronic (or long-term) Hepatitis C, meaning it doesn’t go away.[iv]

Untreated HCV

Untreated chronic HCV can result in cirrhosis of the liver, liver cancer, end-stage liver disease, as well as hepatic encephalopathy (a brain condition that causes confusion, sleepiness, and disorientation). People who have HVC are more likely to develop rheumatoid arthritis, an inflammatory disease that causes pain, swelling, and stiffness in the joints. Some people with HVC develop cryoglobulinemia, which happens when abnormal proteins in the blood solidify in cold conditions. This can result in damage to the blood vessels, nerve damage, skin sores, and even stroke or heart attack. Some people with HVC develop glomerulonephritis, a type of inflammation in the part of the kidney that filters waste from the bloodstream. If left untreated, this can cause the kidneys to shut down. HVC has also been found to be associated with type 2 diabetes. The virus can increase the body’s insulin resistance, causing blood sugar problems. The insulin resistance may also lead to a faster progression of the HVC. Other symptoms that can develop with HVC are jaundice (yellowing of the skin), gallstones, thyroid disease, and a blood vessel problem known as portal hypertension.[v]

HCV and the Veterans Administration

An estimated 230,000 veterans, mostly Vietnam era veterans are infected with HCV, where it was spread by battlefield
blood transfusions and vaccinations[^vi], as well as tattoos, IV drug use and unprotected sexual contact. [^vii] The VA has taken responsibility for HCV infections found in Vietnam era veterans largely due to the wide-spread use of “jet-injectors” for mass immunizations.[^viii]

The United States Veteran Administration (VA) health care system has dramatically increased the number of HCV treatments that it provides. In March of 2016 the VA announced that it had authorization to spend up to $1 Billion on HCV drugs in 2016, approximately 17% of its annual pharmaceutical spending.[^ix]

The estimated remaining cost for the medications used in treating these veterans is approximately $10 billion, so at current funding rates this program will consume a significant portion of VA pharmaceutical funding for the next decade. Patent protection for the most common HCV treatments do not start to expire until 2029, by which time a significant number of Vietnam vets will be treated or deceased.

Both Gilead Sciences Inc. and Merck & Co, Inc. have effective DAAs in the market. There is fierce competition to sell these high margin products, which has resulted in some downward price pressure.[^x] Cost of each company’s treatment has been adjusted for sale to the VA, but still, each is more than $50K per veteran patient.

### About Gilead[^xi]

Gilead Sciences, Inc., is a research-based biopharmaceutical company that discovers, develops and commercializes medicines in areas of unmet medical need. The Company’s portfolio of products and pipeline of investigational drugs includes treatments for Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome (HIV/AIDS), liver diseases, cancer, inflammatory and respiratory diseases and cardiovascular conditions.

#### Gilead and Liver Diseases

The Company’s products for patients with liver diseases include Vemlidy, Epclusa, Harvoni, Sovaldi, Viread and Hepsera. Epclusa is also the first single-tablet regimen approved for the treatment of patients with HCV genotype 2 and 3, without the need for ribavirin. Harvoni is an oral formulation of ledipasvir and sofosbuvir dosed once a day for the treatment of genotypes 1, 4, 5 and 6, HCV/HIV-1 co-infection, HCV genotype 1 and 4 liver transplant recipients, and genotype 1-infected patients with decompensated cirrhosis. In Europe, Harvoni is also indicated for certain patients with HCV genotype 4 infection, HCV genotype 3 infection with cirrhosis and/or prior treatment failure and those with HCV/HIV-1 co-infection.

Sovaldi is an oral formulation of sofosbuvir dosed once a day for the treatment of HCV as a component of a combination antiviral treatment regimen.

#### HARVONI (ledipasvir/sofosbuvir)[^xii]

October 2014, The FDA approved Gilead’s Harvoni, a combination pill to treat Hepatitis C, for people with HCV genotype 1. Harvoni is estimated to account for $12BN in sales for 2017, about ½ of total company revenue.[^xiii] A little more than ½ of that sales volume is from the US. Harvoni seems to be the most effective treatment for the majority of HCV patients, but both Harvoni and Merck’s Zepatier are more than 90% effective.[^xiv]

Gilead has come under fire from lawmakers, who have accused the company of price-gouging. The company had been charging the VA up to $68,000 for a treatment regimen that costs about $1,400 to make. As a result, the VA, could afford to treat only the sickest patients.[^xv] Gilead has made a deal with the VA to reduce the cost of Harvoni to an estimated $50,000 per treatment.

### About Merck[^xvi]

Merck & Co., Inc. is a global healthcare company. The Company offers health solutions through its prescription medicines, vaccines, biologic therapies and animal health products. It operates through four segments: Pharmaceutical, Animal Health, Healthcare Services and Alliances.[^xvii]
In January 2016, The FDA approved Zepatier to treat adults with chronic HCV genotypes 1 or 4 infection, including those with compensated cirrhosis, HIV-1 co-infection, or severe kidney disease and on dialysis. Zepatier is estimated to be a $500MM product in 2017 and a $1BN product in 2018.[xix]

Merck executives said they priced the medication "to broaden and accelerate access to treatment for patients covered in commercial or public plans, including our country’s veterans."

“This is a good example of how government and industry can work together toward a shared goal in the best interests of public health — particularly for our veterans who are so deserving,” Merck chairman and CEO Kenneth Frazier said.[xx]

[ii] What is Hep C: https://www.cdc.gov/hepatitis/hcv/
[ix] VA to expand HVC Treatment Press release: https://www.va.gov/opa/pressrel/pressrelease.cfm?id=2762 (attached as Exhibit 1)
[x] Pricing and competition: http://www.fiercepharma.com/marketing/merck-s-aggressive-hep-c-pricing-helps-it-steal-share-q1
[xii] Harvoni: https://www.drugs.com/harvoni.html
[xviii] Zepatier: https://www.drugs.com/zepatier.html