Uploaded to the VFC Website

2016

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

Repatha (evolocumab) injection gets FDA approval for high cholesterol

Published on October 9, 2015 at 2:38 AM

The U.S. Food and Drug Administration today approved Repatha (evolocumab) injection for some patients who are unable to get their low-density lipoprotein (LDL) cholesterol under control with current treatment options.

Repatha, the second drug approved in a new class of drugs known as PCSK9 inhibitors, is approved for use in addition to diet and maximally-tolerated statin therapy in adult patients with heterozygous familial hypercholesterolemia (HeFH), homozygous familial hypercholesterolemia (HoFH), or clinical atherosclerotic cardiovascular disease, such as heart attacks or strokes, who require additional lowering of LDL cholesterol.

Familial hypercholesterolemia (encompassing both HeFH and HoFH) is an inherited condition that causes high levels of LDL cholesterol. A high level of LDL cholesterol in the blood is linked to cardiovascular or heart disease. Heart disease is the number one cause of death for Americans, both men and women. According to the Centers for Disease Control and Prevention, about 610,000 people die of heart disease in the United States every year– that equals one in every four deaths.

"Repatha provides another treatment option in this new class of drugs for patients with familial hypercholesterolemia or with known cardiovascular disease who have not been able to lower their LDL cholesterol enough with statins," said John Jenkins, M.D., director of the Office of New Drugs, Center for Drug Evaluation and Research. "Cardiovascular disease is a serious threat to the health of Americans, and the FDA is committed to facilitating the development and approval of effective and safe drugs to address this important public health problem."

Repatha is an antibody that targets a specific protein, called PCSK9. PCSK9 reduces the number of receptors on the liver that remove LDL cholesterol from the blood. By blocking PCSK9's ability to work, more receptors are available to get rid of LDL cholesterol from the blood and, as a result, lower LDL cholesterol levels.

The efficacy and safety of Repatha were evaluated in one 52-week placebo-controlled trial and eight 12-week placebo-controlled trials in participants with primary hyperlipidemia, including two that specifically enrolled participants with HeFH and one that enrolled participants with HoFH. In one of the 12-week studies, 329 participants with HeFH, who required additional lowering of LDL cholesterol despite statins with or without other lipid-lowering therapies, were randomized to receive Repatha or placebo for 12 weeks. Participants taking Repatha had an average reduction in LDL cholesterol of approximately 60 percent, compared to placebo.

The most common side effects of Repatha include nasopharyngitis, upper respiratory tract infection, flu, back pain, and reactions such as redness, pain, or bruising where the injection is given. Allergic reactions, such as rash and hives, have been reported with the use of Repatha. Patients should stop using Repatha and get medical help if they experience symptoms of a serious allergic reaction.

Multiple clinical trials have demonstrated that statins lower the risk of having a heart attack or stroke. A trial evaluating the effect of adding Repatha to statins for reducing cardiovascular risk is ongoing.

Source:
http://www.fda.gov
