From: "jeffrey E." <jeevacation@gmail.com>
To: Sultan Bin Sulayem <[redacted]>
Subject: Re: FDA Approved a Potent and Pricey Cholesterol lowering drug today
Date: Fri, 24 Jul 2015 20:47:39 +0000

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yes, it requires a shot, its not a pill and so far no long term effects known

On Fri, Jul 24, 2015 at 4:37 PM, Sultan Bin Sulayem <[redacted]> wrote:

> Have you heard of this colestrol
>
> Jul 24, 2015 @ 3:23 PM **1,169** views
>
> # The FDA Approves A Potent And Pricey Cholesterol-Lowering Shot
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> Matthew Herper ,
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> Forbes Staff
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> I cover science and medicine, and believe this is biology's century.
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> The Food and Drug Administration has approved Praluent, a new medicine to lower cholesterol in people who have established heart disease, for people whose risk of a heart attack or stroke is not being adequately controlled by existing drugs called statins.
> It might be a big step in the battle against heart disease – and the approval is a triumph for Regeneron Pharmaceuticals, the Tarrytown, [redacted]-based biotechnology company that invented it. Praluent is likely to be more widely used, and to cost more, than Wall Steet analysts expected. That also means it could be a big cost down the line.
> "Obviously, the class is one of the biggest developments in cardiology in the last decade, that will allow us to treat patients who have been extremely difficult to treat with high levels of LDL cholesterol," says Steven Nissen, chairman of cardiology at the Cleveland Clinic. "It's very promising."
> But it will also be very expensive, say Troy Brennan, the chief medical officer of CVS Caremark, the giant pharmacy benefits manager."If these drugs are used as broadly as they could be used, they are going to be by far the most expensive drug class," Brennan says.
> Praluent, an injection, lowers low-density lipoprotein, the so-called "bad cholesterol", by as much as 60%, far more than the statin drugs alone. It is the first drug to work by targeting a protein called PCSK9. Mutations in the gene that makes it can result in patients having lower cholesterol and a dramatically lower lifetime risk of heart attacks. A rival medicine from Amgen is also expected to be approved soon. The FDA is clearing Praluent for patients with heterozygous familial hypercholesterolemia, a genetic condition that causes high cholesterol, and for people who have heart disease, like those who've had heart attacks or strokes, who are already taking the maximum dose of a statin they can tolerate.
> Regeneron and its marketing partner Sanofi say Praluent will have a wholesale cost of $40 a day, or $14,600 a year, for either of two doses, 75 milligrams or 150 mgs. It's likely that insurance companies will get a significant discount, because Amgen and Regeneron will compete by giving the insurers rebates.
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"We don't want the noise about these drugs to be price," says Leonard Schleifer, the chief executive and founder of Regeneron. "We have to make sure that people get access to the drug for a fair price if they're insured, for free if they're not insured, or at a discount if they're under-insured."

Praluent's price is 46% higher than that forecast by Evercore ISI, an investment bank, and it is being approved for a larger group of patients than many Wall Street analysts expected following a meeting convened by the FDA to analyze the data on the drug. Some doctors argued its use should be restricted mainly to patients with FH. But Mark Schoenebaum, Evercore ISI's pharmaceutical analyst, says that investors were initially disappointed because they had hoped the FDA would greenlight the drug for an even broader group. Regeneron shares were down 2.5% in afternoon trading before they were halted pending news.

But doctors may prescribe the drug more widely than the label suggests. A survey of physicians published this morning by Geoffrey Porges, an biotechnology analyst at investment bank Sanford C. Bernstein, found that they would use the drug in 30% to 40% of patients who had already had heart attacks. He wrote that 2020 sales of Praluent could be as high as $4.8 billion.

In the survey, doctors expressed a preference for Praluent. One advantage of Regeneron's drug is that doctors will be able to start it at a lower, 75 milligram dose.

Schleifer, who is a medical doctor and, incidentally, a billionaire thanks to his Regeneron stake, says that the company expects that as many as 8 million people who don't have their cholesterol well-controlled could be candidates for Praluent. He emphasized, though, that until larger studies prove the drug prevents heart attacks and strokes patients should always choose statins first. It will have sales representatives a

Insurance companies and pharmacy benefit managers, who help insurers and employers manage drug costs, are going to do their best to restrict use of Praluent, though. Brennan, the CVS Caremark executive, says that he expects patients will need to have medical records documenting that they have already taken statins. Those not taking statins would need a blood test confirming that a statin caused elevations in muscle or liver enzymes, not just complaints that they were achy. "We're not trying to replace statins," says Schliefer, the Regeneron CEO.

Most people who have muscle problems from statins do not have those elevated muscle enzymes, says Nissen, the Cleveland Clinic cardiologist, who is conducting a clinical trial Amgen and Pfizer, which is also developing a similar cholesterol drug. He says he has patients who are "desperate" to take a statin but who cannot tolerate it because of muscle pain but do not have elevated muscle enzymes.

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"Dehspite significant progress over the last decades, high cholesterol remains a leading concern in the U.S. and globally," said Olivier Brandicourt, [redacted]., Chief Executive Officer, Sanofi. "Praluent demonstrates the power of the Sanofi and Regeneron alliance to deliver a first-in-class therapy in the U.S. for patients in need. Sanofi has a strong cardiovascular heritage and dedication to these patients, and we look forward to working with other regulatory authorities to make Praluent available to patients worldwide."

"We are grateful to the thousands of patients and investigators worldwide who participated in the ODYSSEY clinical trial program," said Leonard S. Schleifer, [redacted]., [redacted]., Founder, President, and Chief Executive Officer, Regeneron. "Praluent represents the culmination of more than a decade of tireless work to translate the genetic-based discovery of PCSK9 into an innovative medicine that brings meaningful value to patients."

The approval of Praluent was based on data from the pivotal Phase 3 ODYSSEY program, which showed consistent, positive results compared to placebo, which included current standard of care therapy (statins). In the ODYSSEY LONG TERM trial which evaluated Praluent 150 mg every two weeks, Praluent reduced LDL cholesterol by 58 percent versus placebo at week 24 when added to current standard of care, including maximally tolerated statins. In ODYSSEY COMBO I, Praluent 75 mg every two weeks as an adjunct to statins reduced LDL cholesterol by an additional 46 percent compared to placebo at week 12. At week 24 in the same trial, Praluent reduced LDL cholesterol by 43 percent compared to placebo. In this study, if additional LDL cholesterol lowering was required based on pre-specified criteria at week 8, Praluent was up-titrated to 150 mg at week 12 for the remainder of the trial. Eighty-three percent of patients remained on their initial 75 mg dose.

Praluent is generally well-tolerated with an acceptable safety profile. Local injection site reactions including redness, itching, swelling or pain/tenderness where the injection is given were the most common events (7.2 percent with Praluent versus 5.1 percent with placebo) and resulted in a low discontinuation rate that was comparable to placebo (0.2 percent with Praluent versus 0.4 percent with placebo). Patients receiving Praluent had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo. Other common adverse events occurring more frequently in patients with Praluent than placebo included symptoms of the common cold and flu or flu-like symptoms.

The companies carefully considered the potential medical value that Praluent offers patients in determining the Wholesale Acquisition Cost (WAC). The U.S. WAC price of Praluent is $40 per day ($1,120 every 28 days) for both the 75 mg and 150 mg doses, making Praluent the lowest priced patient-administered monoclonal antibody therapy on an annualized basis. Actual costs to patients, payers and health systems are anticipated to be lower as WAC pricing does not reflect discounts or rebates. Out-of-pocket costs to patients will vary depending on insurance status and eligibility for patient assistance.

Sanofi and Regeneron are committed to ensuring that patients in the U.S. who are prescribed Praluent are able to access the medicine and receive the support they may need. The companies will launch a comprehensive program that offers support, training and follow up for patients at every step of the process. The program will provide patient assistance to uninsured or underinsured patients, including providing free medicine to eligible patients, and can help identify coverage options for out-of-pocket costs. Additional services include educational information, clinical support for physicians, nurses and pharmacists, as well as reimbursement services, including co-pay support for eligible patients and information about insurance eligibility support. For more information, please call 1-844-PRALUENT (1-844-772-5836Ca).

Earlier today, the companies announced that the European Medicine Agency's (EMA's) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for the marketing authorization of Praluent, recommending its approval for use in certain adult patients with hypercholesterolemia. The European Commission (EC) is expected to make a final decision on the Marketing Authorization Application for Praluent in the European Union in September 2015.

Investor Relations Conference Call on Praluent

Sanofi and Regeneron will be hosting a conference call for the financial community on Praluent® (alirocumab) Injection for the treatment of high LDL cholesterol in adult patients. The conference call will take place on Friday, July 24, 2015 (21:30 CET / 20:30 BST/ 15:30 EDT / 12:30 PDT).

The call will be available through audio webcast at [redacted] and [redacted] and also via the following telephone numbers:

France:	[redacted]
UK:	
U.S.:	
	Access code: 81662098

[redacted]

ODYSSEY Program
The ODYSSEY Phase 3 program is one of the most comprehensive clinical trial programs ever conducted for an investigational LDL cholesterol lowering therapy. The program includes 14 global Phase 3 trials evaluating more than 23,500 patients. The primary efficacy end point in all of the studies was the mean percent reduction from baseline in LDL cholesterol at week 24 compared to placebo (maximally tolerated statin therapy); all of the completed studies met their primary endpoint. A significantly higher proportion of patients achieved LDL cholesterol of less than 70 mg/dL in the Praluent group as compared to placebo at both week 12 and week 24. The ongoing ODYSSEY OUTCOMES trial will prospectively evaluate the cardiovascular benefits of Praluent in approximately 18,000 patients.

Important Safety Information
Do not use PRALUENT if you are allergic to alirocumab or to any of the ingredients in PRALUENT.
Before you start using PRALUENT, tell your healthcare provider about all your medical conditions, including allergies, and if you are pregnant or plan to become pregnant or if you are breastfeeding or plan to breastfeed.
Tell your healthcare provider or pharmacist about any prescription and over-the-counter medicines you are taking or plan to take, including natural or herbal remedies.
PRALUENT can cause serious side effects, including allergic reactions that can be severe and require treatment in a hospital. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any symptoms of an allergic reaction including a severe rash, redness, severe itching, a swollen face or trouble breathing.
The most common side effects of PRALUENT include: redness, itching, swelling, or pain/tenderness at the injection site, symptoms of the common cold, and flu or flu-like symptoms. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
Talk to your doctor about the right way to prepare and give yourself a PRALUENT injection and follow the "Instructions for Use" that comes with Praluent.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088Ca

Please click here for the full Prescribing Information.

About Sanofi
Sanofi, an integrated global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).