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Will Regeneron's New Drug Break The Bank?

Regeneron and Sanofi's newly-launched Praluent could cause healthcare costs to soar.



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TMFEBCapital

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 Money Inside Pills Flickr User Chris Potter

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Nose-curling, sky-high drug prices are drawing everyone's ire, and while a lot of that fury is being directed at recently-launched hepatitis C drugs, a new target could soon emerge in the form of a new class of cholesterol busting medicines that includes **Regeneron** (NASDAQ:REGN) and **Sanofi SA's** (NYSE:SNY) recently-approved Praluent.

The FDA gave Regeneron and Sanofi a green light to begin selling Praluent last week, and the two companies wasted little time before announcing that their new drug will cost a jaw-dropping \$14,600 per year.

Innovating treatment

There's no question that there's a massive need for new therapeutic approaches that can reduce the risk of heart disease. More than 600,000 Americans die from heart disease every year, making it the number one cause of death among both men *and* women.

For decades, cholesterol-lowering statins have been the primary weapon used by doctors to battle heart disease. Statins, which work by reducing cholesterol production in the liver, have been proven to both lower bad cholesterol levels and reduce the risk of major cardiac events, such as heart attack and stroke. As a result, statins have become the most widely-prescribed drugs in the United States, with millions of patients taking them every year.

Although statins do a solid job of reducing cholesterol levels, they don't work for everyone. Some people don't respond to statin therapy, others discontinue using them because of their side effects, and some achieve only a marginal benefit from them.

For that reason, Regeneron and Sanofi believe that Praluent could become part of a new standard of care for these patients.

As a PCSK9 inhibitor, Praluent works differently from statins by blocking the activity of a protein that is responsible for breaking down bad cholesterol receptors in the liver, in turn improving the body's ability to flush cholesterol out of the blood stream.

During clinical trials, patients taking a combination of Praluent and statins saw their bad cholesterol drop by 62% versus statins alone, and that kind of efficacy suggests that combining a PCSK9 inhibitor like Praluent and a statin delivers an incredibly potent one-two punch.

Not for everyone (yet)

Although Praluent put up strong results in clinical trials, its use -- at least initially -- will be limited primarily to people with stubbornly high cholesterol, such as those suffering from genetic mutations like homozygous familial hypercholesterolemia, or HoFH, and heterozygous familial hypercholesterolemia, or HeFH, and to people who have already suffered a heart attack or stroke and require additional intervention.

Although that is a more limited pool of patients than statins treat today, industry watchers think that ongoing studies evaluating PCSK9 inhibitors more thoroughly could lead to it becoming a standard used to treat all patients at risk of heart disease.

If so, then Praluent and other PCSK9 inhibitors could pose a major threat to healthcare payers, who would likely have to respond to surging expenses with increasingly larger monthly insurance premiums or patient co-pays.

According to pharmacy benefit manager **Express Scripts**, a company that manages drug programs for millions of patients, up to 71 million Americans could someday qualify for treatment with PCSK9 inhibitors like Praluent. At its current price, treating all those patients would cost more than \$1 trillion annually. For comparison, Americans currently spend about \$374 billion per year on all their medications.

Looking ahead

Early on, Regeneron and Sanofi estimate that the addressable patient pool likely ranges between 8 million and 10 million Americans. If the companies succeed in treating 500,000 of those patients in the coming year, Praluent's sales could eclipse \$7 billion.

Of course, that number doesn't reflect the likely discounts that will be offered to payers, so the amount could prove to be significantly lower than that. Also, other companies are likely to launch their own PCSK9 drugs soon, including **Amgen**, which is expecting an FDA decision later this month. As new competitors roll-out their products, it should result in larger gross to net price cuts that will bring down the amount spent on these drugs too.

Regardless, Regeneron and Sanofi's newly-approved drug and the billions of dollars in potential revenue that could be coming due to its lofty price tag sets the stage for yet another contentious debate over whether or not drug prices are justified.

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