

By Allison Connolly

June 28 (Bloomberg) -- Fish oil has been touted as useful for everything from growing hair to treating clinical depression. Now drug makers are stepping up their promotion of its benefits for treating heart disease.

AstraZeneca Plc, Amarin Corp. and GlaxoSmithKline Plc are betting the market for prescription fish-oil pills will follow the success of cholesterol-lowering drugs including Lipitor, once the world's best-selling medicine with revenue of \$13 billion a year.

Heart disease remains the world's biggest killer, accounting for 30 percent of global deaths, even as statins and other treatments have become more widely used. Now that Lipitor and many other statins have cheaper, generic competitors, drugmakers are looking for new ways to tackle the array of conditions that can lead to heart disease, including coupling triglyceride treatments with existing cholesterol-lowering pills for a one-two punch.

"The number of people with elevated triglyceride levels is rising rapidly across the world, due in part to the increasing prevalence of obesity and diabetes," AstraZeneca Chief Executive Officer Pascal Soriot said when he bought fish-oil pill maker Omthera Pharmaceuticals Inc. for \$443 million last month. "There is a clear need for effective and convenient alternatives to some of the existing treatments."

Evidence Lacking

Unlike capsules that can be bought in health-food stores, the drugmakers' products are only available with a prescription, are highly concentrated and undergo a several-step purification process approved by the U.S. Food and Drug Administration.

There's a hitch, however. Statins have been proven in studies to cut heart risk. The benefits of fish-oil pills are less certain. Though they target triglycerides, fatty substances in the blood that have been linked to a higher risk of heart attacks, little evidence exists that the pills prevent heart attacks.

"It's very unclear what role fatty acids play for cardiac patients," Mark Urman, a member of the American College of Cardiology Prevention Committee and practicing cardiologist at Cedars-Sinai Heart Institute, said in an interview. "The lab tests look better, but has it done the patient any good?"

Mixed Results

Study results have been mixed. Japanese research on almost 19,000 people who took fish oil with a statin had a 19 percent lower risk of heart attacks, sudden cardiac death and other major coronary events, compared with those who took a statin alone.

A late-stage trial of Vascepa sponsored by Amarin found that it cut triglyceride levels by almost 22 percent at a 4-gram dose and 10 percent at a 2-gram dose without raising cholesterol levels in patients taking statins.

Other trials have shown little or no benefit. A study of more than 12,500 patients showed that a 1-gram daily dose of omega-3 fatty acids didn't prevent death or other cardiovascular events compared with placebo, according to an article in the New England Journal of Medicine in June 2012. And a review of data from 68,000 patients who took fish oil supplements over 24 years showed no reduction in risk of heart attack, stroke and death, the Journal of the American Medical Association said in September.

Market Opportunity

If cleared by regulators, AstraZeneca's Epanova would be the latest prescription pill to enter the market. It would bolster the London-based company's best-selling drug, a statin called Crestor, once it faces generic competition in 2016. While the drugmaker is still formulating its strategy, the Crestor sales team will pitch the product as an added benefit to the statin, said William Mongan, AstraZeneca's executive director of U.S. business development.

Amarin won U.S. approval to market Vascepa to people who have triglyceride levels of 500 milligrams per deciliter of blood or greater, a group of about 4 million people, according to the Dublin-based drugmaker. It's also seeking clearance to sell Vascepa for an additional 40 million people who have triglyceride levels between 200 milligrams and 500 milligrams, a "multi-billion dollar market opportunity."

Glaxo, whose Lovaza has brought in almost 2.5 billion pounds (\$3.8 billion) in sales in the past five years, is more guarded about the market's prospects. In its 2012 annual report, the London-based drugmaker said the market had declined by 7 percent compared with 2011. Economic pressures have resulted in fewer doctor visits and reduced testing for conditions such as very high triglycerides that don't have any obvious symptoms, Glaxo said.

Payers Skeptical

Without much evidence to support the claim that the pills cut heart risk, health-care purchasers remain skeptical of the benefits. The U.K.'s medical spending watchdog, the National Institute for Health and Care Excellence, this month said it no longer recommends that heart attack survivors take fish-oil pills to prevent further heart attacks, citing their "minimal" benefit.

"It should be clear that they are not alternatives to statins," Cedars-Sinai's Urman said. He prescribes them predominately for patients who are in danger of developing pancreatitis, a painful inflammation of the pancreas caused by elevated triglyceride levels.

Catching Lovaza

Vascepa has a long way to go to catch Lovaza. The drug had \$4.3 million in sales between January and the end of April compared with \$424.6 million for Lovaza, according to Symphony Health, a U.S. consulting firm. Amarin had to hire its own sales force after failing to find either a buyer for the company or a partner to help market Vascepa.

Amarin has fallen 60 percent in the last year and closed yesterday at \$5.68, giving the drugmaker a market value of \$854 million.

Analysts predict Lovaza sales will decline about 1.4 percent this year, according to the average of eight estimates compiled by Bloomberg.

"Do we need more preparations on the market? No," said Robert Eckel, director of the lipid clinic at the University of Colorado Hospital at the Anschutz Medical Campus in Aurora, Colorado, and past president of the American Heart Association.

"Do we have all of the answers about whether they are beneficial or not? No, we don't have those yet."

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