Johnson & Johnson: Stelara fares well in Crohn's disease

19 October 2015, byLinda A. Johnson

Johnson & Johnson's immune disorder drug Stelara significantly reduced symptoms of the inflammatory bowel condition Crohn's disease with just one infusion in about half the patients tested, according to the company.

The results, released Monday, are the first from multiple late-stage studies—normally the last stage before seeking regulatory approval for Crohn's, which J&J plans to do later this year. Stelara, on the market since 2009, is approved for treating plaque psoriasis and psoriatic arthritis.

Besides giving Crohn's patients a new option, the additional approval could shore up vulnerable sales in J&J's biggest franchise, drugs for disorders in which the immune system attacks the body's own tissue. That also could give J&J a boost in the fiercely competitive category, which is led by the world's top-selling drug, Humira.

Biologic drugs Stelara, Simponi and Remicade, J&J's oldest immune disorder medicine, bring the company more than $10 billion a year combined and treat conditions including rheumatoid arthritis and ulcerative colitis.

They compete in various conditions with rival AbbVie Inc.'s Humira, which has more than $13 billion in annual sales and treats seven immune disorders, as well as other drugs including Enbrel, sold by Amgen Inc. and Pfizer Inc.

The injectable drugs have various dosing schedules and work by different mechanisms, neutralizing different immune system proteins to reduce the inflammation that triggers symptoms and so limit complications.

They're all genetically engineered, powerful and can cause serious side effects, including liver and heart problems, some cancers and infections that can be deadly. They're also expensive: For psoriasis patients, Stelara costs $32,500 to $65,000 a year without insurance, depending on the dose.

J&J's Remicade, approved for Crohn's and five other disorders, is its top drug with sales of about $6.5 billion annually. That's dipping because biosimilar competition—sort-of generic versions of biologic drugs "manufactured" in living cells—has begun elsewhere. It could hit in the U.S. after Remicade's patent expires in September 2018.

In the company-funded Stelara study, which gave an "induction" treatment meant to bring Crohn's under control, 628 patients got a single infusion of Stelara at one of two doses, or a placebo infusion. Eight weeks later, 47 percent of patients getting a low Stelara dose and 58 percent getting a high dose had major symptom improvement, compared with 32 percent of those receiving placebo.

One of the other soon-to-be-completed Crohn's studies is giving patients maintenance doses of Stelara every 12 weeks to see how they fare longer term.

About 700,000 Americans have Crohn's, which is incurable and causes abdominal pain, diarrhea, rectal bleeding and other nasty symptoms. Its cause is unknown.