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First 'biosimilar' of a biologic drug reaches US, finally

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Years after discounted versions of some of the most expensive drugs ever went on sale in other countries, they're finally coming to the world's biggest medicine market.

Last week brought the first U.S. launch in a new category called "biosimilars." They're near-copies of powerful prescription drugs known as biologics "manufactured" in living cells.

Biologics are injected or infused medicines for very serious conditions such as cancer and immune system disorders. They can cost $100,000 or more annually.

Swiss drugmaker Novartis AG last Thursday launched Zarxio, a biosimilar version of Amgen Inc.'s Neupogen, which boosts white blood cell production to prevent infections in certain cancer and other patients.

Here are some questions and answers on biologic drugs and biosimilars:

—What are they? Unlike traditional pills made by mixing chemicals, biologic drugs are made from proteins grown in living cells, nourished in nutrient broths inside sterile bioreactor tanks. The process can take weeks and requires precise control of temperature, oxygen level and other conditions. The proteins are then filtered out of the cells, purified, mixed with a sterile injectable solution and put into vials or syringes. Biosimilars are made the same way.

Biologic drugs include vaccines and other complex medicines, including ones that incorporate antibodies to target where they're needed. Last year, six of the 10 bestselling medicines globally were biologics, with about $49 billion in combined sales.

—Are biosimilars identical to brand-name versions? They're close, but not exact copies, due to the complexity of manufacturing and subtle differences between cell batches used in production.

How much cheaper will they be? The Novartis generics business, Sandoz, is selling Zarxio for 15 percent less than Neupogen, which costs about $325 to $500 per day, depending on dose. Experts predict biosimilar discounts of 15 percent to 30 percent in the U.S. In Europe, where governments regulate prices, discounts are higher.

By comparison, generic pills often cost 90 percent less than brand-name drugs.

—Will biosimilar prices fall? That might begin within several years, after the U.S. gets multiple biosimilar versions of the top biologic drugs, mainly ones that reduce inflammation in patients with rheumatoid arthritis and other immune disorders, analysts say. Insurance plans would then have leverage to seek bigger discounts from biosimilar drugmakers.

Edward Jones analyst Ashtyn Evans says those factors could force down prices for original biologic drugs.

Their prices have risen steadily for years, notes WBB Securities analyst Steve Brozak, even though technology improvements have reduced manufacturing costs for these "cash cows" by roughly two-thirds since the 1990s.

—Are they available in other countries? About two dozen European

Union countries, Australia, Brazil, Canada, India, Japan, Korea and Turkey all have biosimilars on sale. Those include versions of popular insulin Lantus, human growth hormone and drugs for macular degeneration, anemia in chemotherapy and dialysis patients, and rheumatoid arthritis, psoriasis and other immune disorders.

—Why did the U.S. approval take so long? Europe approved the first biologic drug in 2006. In the U.S., longer patent durations are blocking copycats of many top biologic drugs for a few more years. Also, Congress didn't grant the Food and Drug Administration power to set regulations governing approval of biosimilars until 2010, and the FDA finalized those rules recently. That paved the way for Zarxio's approval in March, but Amgen held up its launch with litigation until this month.

—Who's developing biosimilars? Top pharmaceutical companies including Novartis, Pfizer Inc. and Merck & Co., which all make their own biologic drugs, are developing biosimilars of rival companies' top biologics. Merck and partner Samsung Bioepis Co Ltd. got their first biosimilar approval Monday, in South Korea for a version of blockbuster immune disorder treatment Enbrel. Merck plans to apply for U.S. approval of others starting this year or next. Pfizer just entered the field by buying Hospira, a top maker of biosimilar drugs.

Biologic drug maker Amgen Inc., whose bestselling medicines face biosimilar competition from multiple drugmakers, is developing nine biosimilar versions of rivals' top biologic drugs, including four for various cancers. Amgen expects to launch the first in 2017.

—How much money is involved? Market research firm GBI Research predicts global biosimilar sales will hit $20 billion by year's end—about 10 percent of all biologic drug sales—and up to $55 billion by 2020. It says copycats of about 150 biologics are in development. Investment research firm Morningstar Inc. forecasts biosimilars will reduce global

sales for the top 10 biologic drugs from a combined $62 billion last year to $35 billion in 2020. While the revenue pie won't decrease that much, due to more patients starting on biosimilars, revenue for companies that created biologic drugs likely will fall and companies that bring multiple biosimilars to market should see sales spikes.

—What issues are unresolved? Many states are still deciding whether pharmacists can substitute a biosimilar for the original biologic drug without the prescribing doctor's permission, as usually happens with generic pills.

Also, the FDA is finalizing rules on naming biosimilars to distinguish between different manufacturers' products. That's crucial for tracking side effects and other safety issues with the different versions, says Larry LaMotte of Patients for Biologics Safety & Access, a coalition of more than 20 advocacy groups lobbying for protections for patients.

More information: More info: www.BiosimSafety.Org, www.biosimilarsforum.org