

Amgen, UCB halt testing of fracture-healing drug

LINDA A. JOHNSON - AP Business Writer - Associated Press

Biotech giant Amgen Inc. and Belgian drugmaker UCB SA have scrapped plans for late-stage testing of an experimental treatment for accelerated healing of fractures, but will continue testing their drug for a much bigger and potentially lucrative market, treating osteoporosis in postmenopausal women.

UCB said Monday that the partners will not undertake final-stage patient testing of romosozumab, based on partial results from mid-stage patient testing of the drug, as well as recent, tougher regulations for approval of drugs for fracture healing.

The companies said the mid-stage testing of romosozumab, also known as AMG 785, did not uncover any new safety problems, and that those results would be presented at a future medical conference.

UCB's U.S. shares dropped \$1.12, or 3.9 percent, to \$27.60 in afternoon trading, while Amgen shares fell \$1.21, or 1.4 percent, to \$85.09.

Citibank analyst Yaron Werber wrote to investors Monday that the companies' decision "appears to be driven by lack of efficacy in" a one-year study of patients with fractures of the tibia, the larger of the two lower leg bones, plus regulators' recently increased approval standards. Those standards would require two late-stage patient studies, done at each fracture site, that followed fracture patients for two years.

That would drive up development costs "for what we view as a relatively smaller market opportunity," compared to postmenopausal osteoporosis, Werber wrote, adding, "Thus, this appears to be a business decision."

If approved, romosozumab would only be taken for a few months for healing fractures, while women with osteoporosis would take it for a year or more. About 10 million Americans have osteoporosis, and another 34 million are at risk for developing the bone-thinning disease, according to the National Osteoporosis Foundation.

Werber noted it would be difficult to get insurers to cover the drug for fracture healing without proving it worked much better than existing drugs. That's because biologic drugs, produced in living cells rather than by mixing chemicals in a vat, tend to be very expensive.

UBS Securities analyst Matthew Rodden, writing to investors, called the news "a modest downside surprise." He said Amgen officials on Monday said their decision had nothing to do with safety issues, but that the companies decided not to undertake further testing even though a mid-stage study in hip-fracture patients isn't finished.

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Published on Bioscience Technology (<http://www.biosciencetechnology.com>)

Rodden wrote that analysts have not been counting on future revenues from romosozumab for fracture healing. He anticipates it will bring in about \$99 million in worldwide sales for treating osteoporosis in 2017.

Rodden maintains a "Buy" rating on Amgen shares, with a 12-month price target of \$98, also unchanged.

The news comes after Amgen's business review with analysts last Thursday, in which the company announced it is working on developing biosimilar versions of six medicines that it expects to generate about \$2 billion in eventual global sales. The company plans to launch them in the U.S. in 2017.

They include two of the world's top-selling biologic drugs, the anti-inflammatory drugs Humira from Abbvie and Remicade, sold by Johnson & Johnson and Merck & Co. The other four drugs are cancer medicines: the Roche Group's Avastin, Herceptin and Rituxan, and Erbitux from Bristol-Myers Squibb Co. and Eli Lilly and Co.

Biosimilars are similar but not exactly identical to biologic drugs. They're expected to be somewhat cheaper than the original biologic drugs, which often cost tens of thousands of dollars per treatment.

As the world's biggest biotech drugmaker, Amgen appears to have an advantage in the race to get the first biosimilar drugs approved. Amgen has a partnership with one of the world's biggest generic drugmakers, Actavis Inc., which recently changed its name from Watson Pharmaceuticals Inc. after Watson bought Actavis last October.

The Food and Drug Administration last year released regulations for biosimilars to win approval.

Health care data firm IMS Health has estimated the global market for biosimilars will range from \$11 billion to \$25 billion by 2020.

Linda A. Johnson can be followed at http://twitter.com/LindaJ_onPharma [1].

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