

US FDA panel partly backs Amgen bone drug

By Lisa Richwine GAITHERSBURG, Md., Aug 13 (Reuters) - Amgen Inc won partial support from a U.S. panel on Thursday for its most important experimental drug, a new type of medicine to treat the bone-thinning disease osteoporosis, sending its shares up 1 percent in extended trade.

Denosumab is seen as a potential blockbuster and the key to growth at the world's largest biotechnology company after safety concerns hit its flagship anemia medicines.

A Food and Drug Administration advisory committee voted that denosumab's benefits were likely to outweigh risks for treating osteoporosis in post-menopausal women. However, the committee also rejected the drug's use to prevent osteoporosis in elderly women, or to treat or prevent bone loss in certain breast cancer patients.

The panel had yet to decide on a recommendation about whether the Amgen (NASDAQ: [AMGN](#) - [news](#)) drug should be used to treat bone loss in certain prostate cancer patients.

The FDA usually approves drugs that win the backing of advisory panels. A ruling by the agency is due by Oct. 19, but it has missed several drug deadlines in the past year, leading some analysts to anticipate a delay.

Amgen will need to compete in an \$8 billion osteoporosis market with several rival drugs, including low-cost generics, to treat and prevent the bone-thinning disease, which afflicts an estimated 10 million Americans.

Denosumab works differently from current medicines by targeting a protein that activates bone-destroying cells. It is given as a twice-a-year injection.

Analysts see annual sales for denosumab reaching \$2 billion or more.

Global sales of osteoporosis drugs hit about \$8.4 billion in 2008, according to data from IMS Health (NYSE: [RX](#) - [news](#)) .

Shares of the company closed down 2 percent at \$60.86 on the Nasdaq (NASDAQ: [news](#)) but rose in after-hours trade to \$61.34.

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