



# Amgen's denosumab offers hope in rare bone tumours

Tue, Feb 9 2010

\* Small trial offers hope for giant-cell tumour patients

\* Data add to other positive results for denosumab

LONDON, Feb 10 (Reuters) - Amgen's <AMGN.O> bone drug denosumab stops progressive bone destruction and tumour spread in some patients with a rare type of non-malignant bone cancer, according to final data from a small mid-stage trial.

The data, the first to clearly show a promising treatment option for rare inoperable giant-cell tumours (GCT), adds to further recent positive results for the drug, which is seen as a key sales driver for the U.S. biotechnology company.

Shares in Amgen rose on Monday after the firm said final phase trials of denosumab in men with advanced prostate cancer found it works better than Novartis's <NOVN.VX> Zometa to delay and reduce the risk of fractures and other bone complications. [ID:nN08208005]

Denosumab, also known under the brand name Prolia, is the first in a new class designed to inhibit proteins that activate bone-destroying cells.

The drug, which the company is developing as a treatment for cancer patients whose disease has spread to the bone, as well as patients with osteoporosis, is seen by analysts as the most important in Amgen's development pipeline.

Sales are expected to reach \$3.1 billion in 2014, according to consensus forecasts from Thomson Pharma.

The rare bone tumour trial involved 37 patients with non-malignant GCT from the United States, Australia and Europe who were given monthly injections of denosumab plus additional doses on days 8 and 15 of the first month. The patients also took daily calcium and vitamin D supplements.

Findings showed that 86 percent, or 30 of the 35 patients assessed after treatment, responded to the drug, the researchers wrote in *The Lancet Oncology*. Among the 31 patients assessed for other benefits, 84 percent reported benefits like reduced pain and better mobility, and 26 percent had bone repair.

Initial results from 15 patients in the Phase II trial were released at the American Society of Clinical Oncology annual meeting in May 2008.

Almost all patients had side-effects, but a large majority were relatively mild problems like back pain and headaches. Maurice Balke from the University of Witten-Herdecke in Germany, and Jendrik Harges from University Hospital Muenster, Germany, said in a commentary that the data "might change clinical practice in the treatment of complicated GCT of bone."

Denosumab is still under review by the U.S. Food and Drug Administration as a treatment for osteoporosis after the agency asked in October for more information from clinical trials. (Reporting by Kate Kelland; Editing by Louise Heavens)

---

© Thomson Reuters 2010. All rights reserved. Users may download and print extracts of content from this website for their own personal and non-commercial use only. Republication or redistribution of Thomson Reuters content, including by framing or similar means, is expressly prohibited without the prior written consent of Thomson Reuters. Thomson Reuters and its logo are registered trademarks or trademarks of the Thomson Reuters group of companies around the world.

Thomson Reuters journalists are subject to an Editorial Handbook which requires fair presentation and disclosure of relevant interests.