



Amgen to Collaborate With GlaxoSmithKline to Commercialize Denosumab in Europe for Postmenopausal Osteoporosis (PMO)

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Amgen to Retain Full Rights for Denosumab in the United States and Canada and for Oncology Indications in Europe

GlaxoSmithKline Will Commercialize Denosumab for PMO and Oncology in Emerging Markets

THOUSAND OAKS, Calif. and LONDON, July 27 /PRNewswire-FirstCall/ -- Amgen (Nasdaq: AMGN) and GlaxoSmithKline (GSK) today announced a collaboration in which the companies will share commercialization of Amgen's monoclonal antibody denosumab for postmenopausal osteoporosis (PMO) in Europe, Australia, New Zealand and Mexico once the product is approved in these countries. Amgen will commercialize the drug for PMO and oncology in the United States (U.S.) and Canada and for all oncology indications in Europe and specified markets.

GlaxoSmithKline will register and commercialize denosumab for all indications in countries where Amgen does not currently have a commercial presence, including China, Brazil, India and South Korea. The structure of the collaboration allows Amgen the option of an expanded role in commercialization in both Europe and certain emerging markets in the future.

Financial terms of the partnership include an initial payment and near-term commercial milestones to Amgen totaling \$120 million, and ongoing royalties. In Europe, Amgen and GlaxoSmithKline will share profits after accounting for expenses associated with the partnership. In emerging markets, GlaxoSmithKline will be responsible for all commercialization expenses and purchase denosumab from Amgen to meet demand.

The companies' combined commercialization activities will expand access to denosumab, once approved, to patients worldwide who are afflicted by osteoporosis and other bone loss conditions.

"Our collaboration with GlaxoSmithKline will help Amgen bring the promise of denosumab to patients in Europe and other parts of the world more effectively than if we commercialized the drug globally on our own," said Amgen CEO Kevin Sharer. "Amgen and GlaxoSmithKline together are uniquely positioned to help medical providers and patients understand the clinical promise and economic value of denosumab."

"This pioneering treatment that Amgen has developed will be a strong addition to our biopharmaceuticals portfolio," commented Andrew Witty, CEO of GlaxoSmithKline. "The data for denosumab is very encouraging and we believe it will provide significant benefit and value to patients with postmenopausal osteoporosis and other bone disease conditions. Together with Amgen we are committed to increasing worldwide access to this medicine."

In July 2007, Amgen granted Daiichi Sankyo exclusive rights to develop and commercialize denosumab in Japan in PMO and oncology with the potential for additional indications. This arrangement remains in place.

About Denosumab

Denosumab is a fully human monoclonal antibody that targets RANK Ligand and is being investigated for its potential to prevent and treat a broad range of bone disease conditions including osteoporosis, bone metastases and their consequences, cancer treatment-induced bone loss due to hormone ablative therapy, multiple myeloma and bone erosions in rheumatoid arthritis. Denosumab is the first late-stage investigational therapy that specifically inhibits RANK Ligand, an essential mediator of the cells that break down bone. With more than 19,000 patients in trials across indications worldwide, the denosumab development program is the largest ever initiated by Amgen. This broad and deep development program demonstrates Amgen's commitment to researching and delivering pioneering medicines to patients with unmet medical needs.

Amgen has submitted marketing applications for denosumab in the United States, European Union, Canada, Switzerland, and Australia.

About Osteoporosis

Often referred to as the "silent epidemic," osteoporosis is a global problem that is increasing in significance as the population of the world both increases and ages. The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major non-communicable diseases.

Despite availability of osteoporosis treatments for more than 10 years, patients with osteoporosis still experience a substantial number of fractures.⁽¹⁾ Out of an estimated 9 million new osteoporotic fractures globally in 2000, 1.7 million were at the forearm, 1.6 million were at the hip, and 1.4 million were clinical (symptomatic) fractures of the vertebrae in the backbone.⁽²⁾

About Amgen

Amgen discovers, develops, manufactures and delivers innovative human therapeutics. A biotechnology pioneer since 1980, Amgen was one of the first companies to realize the new science's promise by bringing safe and effective medicines from lab, to manufacturing plant, to patient. Amgen therapeutics have changed the practice of medicine, helping millions of people around the world in the fight against cancer, kidney disease, rheumatoid arthritis, and other serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. To learn more about our pioneering science and our vital medicines, visit www.amgen.com.

About GlaxoSmithKline

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For further information please visit www.gsk.com

Forward-Looking Statements

This news release contains forward-looking statements that involve significant risks and uncertainties, including those discussed below and others that can be found in Amgen's Form 10-K for the year ended December 31, 2008, and in its periodic reports on Form 10-Q and Form 8-K. Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Amgen's results may be affected by Amgen's ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments (domestic or foreign) involving current and future products, sales growth of recently launched products, competition from other products (domestic or foreign), difficulties or delays in manufacturing its products. In addition, sales of Amgen products are affected by reimbursement policies imposed by third-party payors, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment as well as U.S. legislation affecting pharmaceutical pricing and reimbursement. Government and others' regulations and reimbursement policies may affect the development, usage and pricing of Amgen products. Furthermore, Amgen's research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Amgen or others could identify safety, side effects or manufacturing problems with Amgen products after they are on the market. Amgen's business may be impacted by government investigations, litigation and products liability claims. Further, while Amgen routinely obtains patents for its products and technology, the protection offered by its patents and patent applications may be challenged, invalidated or circumvented by its competitors. Amgen depends on third parties for a significant portion of its manufacturing capacity for the supply of certain of its current and future products and limits on supply may constrain sales of certain of its current products and product candidate development. In addition, Amgen competes with other companies with respect to some of its marketed products as well as for the discovery and development of new products. Discovery or identification of new product candidates cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate will be successful and become a commercial product. Further, some raw materials, medical devices and component parts for Amgen products are supplied by sole third-party suppliers.

The scientific information discussed in this news release related to Amgen's product candidates is preliminary and investigative. Such product candidates are not approved by the U.S. Food and Drug Administration (FDA) or other regulatory bodies, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only the FDA can determine whether the product candidates are safe and effective for the use(s) being investigated. Healthcare professionals should refer to and rely upon the labeling approved by the FDA or other regulatory bodies for the products, and not the information discussed in this news release.

Cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2008.

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(1) Secular data

(2) Johnell O, Kanis JA. An estimate of the worldwide prevalence and disability associated with osteoporotic fractures. Osteoporosis Int. 2006; 17(12):1726-33

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