

# Amgen And Zhejiang Beta Pharma Announce Planned Joint Venture In China

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# Goal Is to Bring Amgen's Vectibix® (Panitumumab) to Chinese Patients

THOUSAND OAKS, Calif. and ZHEJIANG, China, May 9, 2013 /PRNewswire/ -- Amgen (NASDAQ:AMGN) and Zhejiang Beta Pharma Co., Ltd. (Zhejiang Beta Pharma) today announced that the companies have signed an agreement to form a joint venture to commercialize Amgen's Vectibix<sup>®</sup> (panitumumab) in the Chinese market. Together, Amgen and Zhejiang Beta Pharma aim to quickly and efficiently deliver Vectibix to patients in China.

The joint venture will benefit from Zhejiang Beta Pharma's strong expertise in the development and commercialization of molecularly targeted therapies as well as Zhejiang Beta Pharma's industry-leading oncology sales network in China. Zhejiang Beta Pharma's China capabilities are complementary to Amgen's global expertise in the development and manufacturing of human therapeutics.

"This joint venture brings us one step closer to providing Chinese patients with Amgen's medicines and supports our strategy of expanding in key, fast-growing markets," said Anthony C. Hooper, executive vice president at Amgen. "We are pleased to have the opportunity to join forces with Zhejiang Beta Pharma, a leader in developing and commercializing innovative medicines that shares our goal of making a new treatment option available to colorectal cancer patients in China."

"Amgen is a pioneer and a global leader in the biotech industry. Our partnership with Amgen will be of long-term strategic significance not only for Zhejiang Province, but also for the whole medical community in China," said Lieming Ding, chairman of Zhejiang Beta Pharma. "We share Amgen's passion for developing molecularly targeted therapies for unmet medical needs, and are confident that together we can help many Chinese patients who suffer from colorectal cancer."

"This is an important step forward in Amgen's commitment to the China market," said James Li, vice president and general manager, Amgen Greater China. "We are excited about the formation of our partnership with Zhejiang Beta Pharma and look forward to bringing Vectibix to Chinese patients within the coming years. Amgen's 30-year track record of developing innovative medicines means we are well-positioned to support the development of China's biotech sector. We see this as a clear step that enables Amgen to help China achieve its goals for the biotech industry."

"This is certainly a groundbreaking event for the biotech industry in China," said Yinxiang Wang, CEO of Zhejiang Beta Pharma. "We are pleased to be joining forces with Amgen in the war against cancer."

According to the agreement, the new joint venture will be named Amgen-Beta Pharmaceuticals Co., Ltd. Zhejiang Beta Pharma will own 51 percent and Amgen will own the remaining 49 percent interest in the joint venture. The creation of the joint venture is subject to the satisfaction of certain closing conditions, including the approval of relevant government authorities in China.

### **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, effective medicines from lab to manufacturing plant to patient. Amgen therapeutics have changed the practice of medicine, helping people around the world in the fight against serious illnesses. With a deep and broad pipeline of potential new medicines, Amgen remains committed to advancing science to dramatically improve people's lives. For more information, visit <a href="https://www.amgen.com">www.twitter.com/amgen</a>.

## About Zhejiang Beta Pharma Co., Ltd.

Zhejiang Beta Pharma is a leading innovative pharmaceutical company in China with fully integrated capabilities that include R&D, GMP manufacture, sales and marketing. We were founded in 2003 and are headquartered in Hang-Zhou with R&D operations in Beijing. Over the last 10 years, we have been dedicated to the development of novel therapeutics and launched Icotinib in 2011 for the treatment of NSCLC patients in China. Going forward, we will continue to focus on pharmaceutical innovation so that we can benefit many more patients. For more information, visit <a href="https://www.betapharma.com.cn">www.betapharma.com.cn</a>.

# **About Vectibix**

Vectibix is a prescription medicine used for the treatment of metastatic colorectal cancer (mCRC). It is grouped within a class of medications called biologics, which are therapies derived from human cells. Vectibix is approved in more than 40 countries.

Vectibix is the first fully human anti-epidermal growth factor receptor (EGFR) antibody approved by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic colorectal cancer (mCRC). Vectibix was approved in the U.S. in September 2006 as a single agent for the treatment of metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine, oxaliplatin and irinotecan chemotherapy regimens. Approval is based on progression-free survival; no data demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Retrospective subset analyses of metastatic colorectal cancer trials have not shown a treatment benefit for Vectibix in patients whose tumors had KRAS mutations in codon 12 or 13. Use of Vectibix is not recommended for the treatment of colorectal cancer (CRC) with these mutations.

### Important U.S. Product Safety Information

Vectibix is indicated as a single agent for the treatment of EGFR-expressing, mCRC with disease progression on or following fluoropyrimidine-, oxaliplatin- and irinotecan-containing chemotherapy regimens. The effectiveness of Vectibix as a single agent for the treatment of EGFR-expressing mCRC is based on progression-free survival. Currently, no data demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

Vectibix is not indicated for the treatment of patients with KRAS mutation-positive mCRC or for whom KRAS mCRC status is unknown. Retrospective subset analyses of metastatic colorectal cancer trials have not shown a treatment benefit for Vectibix in patients whose tumors had KRAS mutations in codon 12 or 13.

#### WARNING: DERMATOLOGIC TOXICITY AND INFUSION REACTIONS

Dermatologic Toxicity: Dermatologic toxicities occurred in 89 percent of patients and were severe (NCI-CTC grade 3 or higher) in 12 percent of patients receiving Vectibix monotherapy. [See Dosage and Administration (2.1), Warnings and Precautions (5.1), and Adverse Reactions (6.1)].

Infusion Reactions: Severe infusion reactions occurred in approximately one percent of patients. Fatal infusion reactions occurred in post-marketing experience. [See Dosage and Administration (2.1), Warnings and Precautions (5.2), and Adverse Reactions (6.1, 6.3)].

The most common adverse reactions (≥ 20%) of Vectibix are skin rash with variable presentations, hypomagnesemia, paronychia, fatigue, abdominal pain, nausea and diarrhea, including diarrhea resulting in dehydration.

The most serious adverse reactions of Vectibix are pulmonary fibrosis, pulmonary embolism, severe dermatologic toxicity complicated by infectious sequelae and septic death, infusion reactions, abdominal pain, hypomagnesemia, nausea, vomiting and constipation.

To see the U.S. Vectibix Prescribing Information, visit www.vectibix.com.

#### **Amgen Forward-Looking Statements**

This news release contains forward-looking statements that are based on Amgen's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission (SEC) reports filed by Amgen, including Amgen's most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and Form 8-K. Please refer to Amgen's most recent Form 10-K and any subsequent Forms 10-Q and 8-K for additional information on the uncertainties and risk factors related to Amgen's business. Unless otherwise noted, Amgen is providing this information as of May 9, 2013, and expressly disclaims any duty to update information contained in this news release.

No forward-looking statement can be guaranteed and actual results may differ materially from those Amgen projects. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. Further, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for Amgen to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and Amgen expects similar variability in the future. Amgen develops product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as Amgen may have believed at the time of entering into such relationship. Also, Amgen or others could identify safety, side effects or manufacturing problems with Amgen's products after they are on the market. Amgen's business may be impacted by government investigations, litigation and product liability claims. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. 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, sales of Amgen's products are affected by the reimbursement policies imposed by third-party payers, 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's products. 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. Amgen believes that some of its newer products, product candidates or new indications for existing products, may face competition when and as they are approved and marketed. Amgen's products may compete against products that have lower prices, established reimbursement, superior performance, are easier to administer, or that are otherwise competitive with its products. In addition, 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 and there can be no guarantee of Amgen's ability to obtain or maintain patent protection for its products or product candidates. Amgen cannot guarantee that it will be able to produce commercially successful products or maintain the commercial success of its existing products. Amgen's stock price may be affected by actual or perceived market opportunity, competitive position, and success or failure of its products or product candidates. Further, the discovery of significant problems with a product similar to one of Amgen's products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on Amgen's business and results of operations.

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 State Food and Drug Administration of the People's Republic of China (SFDA), and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Only regulatory agencies such as the U.S. Food and Drug Administration and the SFDA can determine whether the product candidates are safe and effective for use in the applicable region. Healthcare professionals should refer to and rely upon the approved labeling for the products, and not the information discussed in this news release.

### Contacts

Amgen, Thousand Oaks, California Ashleigh Koss, 805-3136151 (US media) Brunswick, +86 (10) 5960-8600 (China media) Arvind Sood, 805-447-1060 (investors)

Zhejiang Beta Pharma, Zhejiang, China Lina Huang (media) lina.huang@betapharma.com.cn

Tel: 010-67869692-610

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