



Today we have excellent news from [ABGENIX \(ABGX\)](#) and [AMGEN \(AMGN\)](#) after the one that came from [OSI \(OSIP\)](#) and [GENENTECH \(DNA\)](#). The news for all these firms is about cancer treatments that took the cancer management into a much higher level than it was for the past quarter of a century. This is the mere reality that is not wrapped in philosophical interpretations that aims at nothing, but misleading investors. Here is the news that we consider breakthroughs that will positively impact cancer treatment.

TARCEVA APPROVED FOR PANCREATIC CANCER

[OSI \(OSIP\) AND GENENTECH \(DNA\)](#) : The FDA expanded the approval of Tarceva drug to include its use against pancreatic cancer along with chemotherapy. Roche Holding Ltd. - the international partner of Tarceva **has applied to European regulators for a similar approval.**

Tarceva® (erlotinib) was approved to be used in combination with gemcitabine for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy.

COMMENTS: The oral, once a day pill, Tarceva, is the first drug in a Phase 3 trial to have shown a **significant improvement in overall survival** when added to **gemcitabine chemotherapy as initial treatment for pancreatic cancer**. Tarceva is a once-daily oral tablet already approved for use in patients with non-small cell lung cancer (NSCLC) whose disease has progressed after one or more courses of chemotherapy. OSI also announced that Roche, its international partner for Tarceva, has submitted a Marketing Authorization Application (MAA) to the European Health Authorities for Tarceva for the treatment of pancreatic cancer.

READ MORE: [FDA Approves Tarceva\(R\) in Combination with Gemcitabine Chemotherapy for Treatment of Locally Advanced, Inoperable or Metastatic Pancreatic Cancer; Tarceva Now Approved for Advanced Non-Small Cell Lung Cancer and Pancreatic Cancer](#)

ABGENIX AND AMGEN

Excellent Phase 3 Trials of Panitumumab For Metastatic Colorectal cancer

Amgen ([AMGN - news](#)) and Abgenix, Inc. ([ABGX - news](#)) today announced that a pivotal Phase 3 study of panitumumab **met the primary endpoint of improving progression-free survival in patients with metastatic colorectal cancer** (mCRC) who had failed standard chemotherapy. In this randomized Phase 3 trial involving 463 patients, those who received panitumumab every two weeks showed a 46 percent decrease in tumor progression rate versus those who received best supportive care alone (p less than 0.00000001).

This result exceeded the pre-specified measure of progression-free survival that the trial was designed to demonstrate (i.e., a 33 percent decrease in tumor progression rate in patients receiving panitumumab versus those receiving best supportive care, as assessed by central radiology review). A secondary endpoint of objective response rate, as assessed by central radiology review, was also met. Analysis of overall patient survival in this study will occur 12 months after the last patient was randomized.

**Complete analyses of data from this trial
will be submitted for presentation at**

a medical meeting in 2006.

Panitumumab is co-developed by Amgen and Abgenix, panitumumab is the first fully human monoclonal antibody that targets the epidermal growth factor receptor (EGFr), a protein that plays an important role in cancer cell signaling. Panitumumab, an IgG2 monoclonal antibody, binds with high affinity to the EGFr. Panitumumab was generated with Abgenix's XenoMouse(R)(1) technology, which creates a fully human monoclonal antibody that contains no murine (mouse) protein. The body's immune system can recognize the mouse protein found in chimeric antibodies as foreign and launches an immune response in the form of infusion reactions, allergic reactions or anaphylaxis. The goal of developing fully human monoclonal antibodies,



which by definition contain no mouse protein, is to offer effective, high affinity therapies that minimize the potential for this type of immune response. Panitumumab is being evaluated in clinical trials as both a monotherapy and in combination with other agents for the treatment of various types of cancer, including colorectal, lung and kidney.

Epidermal Growth Factor Receptor (EGFr)

Although EGFr normally helps regulate the growth of many different cells in the body, it can also **stimulate cancer cells to grow**. In fact, many cancer cells actually require signals mediated by EGFr for their survival. Residing on the surface of these tumor cells, EGFr is activated when naturally occurring proteins in the body, such as epidermal growth factor (EGF) or transforming growth factor alpha (TGF-alpha), bind to it. This binding changes the shape of EGFr, which, in turn, triggers internal cellular signals that stimulate tumor cell growth. Panitumumab binds to EGFr, preventing the natural ligands such as EGF and TGF-alpha from binding to the receptor and interfering with the signals that would otherwise stimulate growth of the cancer cell and allow it to survive.

READ MORE: [Panitumumab Significantly Improves Progression-Free Survival in Phase 3 Randomized Metastatic Colorectal Cancer Study](#)

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