

Genentech Media:	Charlotte Arnold	(650) 467-6800
Genentech Investor:	Susan Morris	(650) 225-6523
OSI Media:	Kim Wittig	(631) 962-2135
OSI Investor:	Kathy Galante	(631) 962-2000

## **Tarceva® In Advanced Non-Small Cell Lung And Advanced Pancreatic Cancers**

Tarceva® (erlotinib), a daily pill, is one of the first targeted treatments approved by the U.S. Food and Drug Administration (FDA) designed to block tumor cell growth by targeting the human epidermal growth factor receptor (EGFR/HER1).

In November 2004, the FDA approved Tarceva for use in people with advanced (metastatic) non-small cell lung cancer whose disease had progressed after initial chemotherapy (second- or third-line treatment). In November 2005, Tarceva used with chemotherapy (gemcitabine) was approved as first-line treatment in people with advanced pancreatic cancer, who had not received prior chemotherapy.<sup>1</sup> The National Comprehensive Cancer Network (NCCN), an alliance of 21 of the world's leading cancer centers, recommends Tarceva as a second-line and third-line treatment for people with advanced non-small cell lung cancer, when given after one or more ineffective chemotherapies.<sup>2</sup> The NCCN recommends Tarceva as a first-line treatment for people with advanced pancreatic cancer, when given with chemotherapy.<sup>2</sup>

Lung cancer is the leading cause of cancer deaths in the United States and pancreatic cancer is the fourth leading cause of cancer deaths.<sup>3</sup>

### **Tarceva “Firsts” In Advanced Non-Small Cell Lung And Pancreatic Cancers**

- Tarceva was the first FDA-approved medicine in more than a decade that may help people with advanced pancreatic cancer live longer, when given with chemotherapy (median survival: 6.4 months vs. 6.0 months; hazard ratio of 0.81; p=0.028)
- Tarceva was the first FDA-approved medicine that may help people with advanced non-small cell lung cancer, including those with non-squamous and squamous cell histologies, who have progressed after initial chemotherapy, live longer (median survival: 6.7 months vs. 4.7 months; hazard ratio 0.73; p<0.001).

### **How Tarceva Works (Proposed Mechanism Of Action)**

- EGFR/HER1 is one of four receptors in the human epidermal growth factor signaling pathway, which has been shown to have a significant impact on cancer cells' ability to grow, spread in the body (metastasize) and survive<sup>5,6</sup>
  - Tarceva is a targeted treatment that specifically inhibits the tyrosine kinase activity of the EGFR/HER1 signaling pathway inside the cell<sup>1,4</sup>
  - The mechanism of Tarceva's clinical antitumor action is not fully characterized

## **Tarceva Clinical Study In Non-Small Cell Lung Cancer**

- In the Phase III study (BR.21), some patients with advanced non-small cell lung cancer who received Tarceva lived longer, when given after one or more prior chemotherapies, compared to patients who received placebo (sugar pill)<sup>1</sup>
  - Thirty-one percent of patients treated with Tarceva survived at least one year compared to 21.5% with placebo
  - Some patients treated with Tarceva lived two months longer (median overall survival: 6.7 months vs. 4.7 months)
  - Some patients treated with Tarceva lived two weeks longer without their disease worsening (median progression-free survival: 9.9 weeks vs. 7.9 weeks)
- Results from two, placebo-controlled Phase III trials in patients with advanced non-small cell lung cancer showed no clinical benefit in first-line treatment with Tarceva plus platinum-based chemotherapy, and its use is not recommended in that setting<sup>1</sup>

## **Tarceva Clinical Study In Pancreatic Cancer**

- In the Phase III study (PA.3), some patients with advanced pancreatic cancer who received Tarceva plus chemotherapy, compared to chemotherapy alone, lived longer<sup>1</sup>
  - Twenty-four percent of people treated with Tarceva survived at least one year
  - Some patients treated with Tarceva and chemotherapy lived two weeks longer (overall survival: 6.4 months vs. 6.0 months)

## **Tarceva Indication**

Tarceva is FDA-approved for use as a monotherapy in patients with locally advanced or metastatic NSCLC whose disease has progressed after one or more courses of chemotherapy.

Results from two multicenter, placebo-controlled, randomized Phase III trials conducted in first-line patients with locally advanced or metastatic NSCLC showed no clinical benefit with the concurrent administration of Tarceva with platinum-based chemotherapy (carboplatin and paclitaxel or gemcitabine and cisplatin) and its use is not recommended in that setting.

## **Tarceva Important Safety Information**

There have been infrequent reports of serious Interstitial Lung Disease (ILD)-like events including deaths in patients taking Tarceva. Serious side effects (including deaths) in patients taking Tarceva include liver and/or kidney problems; gastrointestinal (GI) perforations (the development of a hole in the stomach, small intestine, or large intestine); and severe blistering skin reactions including cases similar to Stevens-Johnson syndrome. Patients taking Tarceva plus gemcitabine were more likely to experience bleeding and clotting problems such as heart attack or stroke.

Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Women should avoid becoming pregnant and avoid breastfeeding while taking Tarceva. Patients should call their doctor right away if they have these signs or symptoms: new or worsening skin rash; serious or ongoing diarrhea, nausea, loss of appetite, vomiting, or stomach pain; new or worsening shortness of breath or cough; fever; eye irritation. Rash and diarrhea were the most common side effects associated with Tarceva in the non-small cell lung cancer clinical study. Fatigue, rash, nausea, loss of appetite, and diarrhea were the most common side effects associated with Tarceva plus gemcitabine therapy in the pancreatic cancer clinical study.

For full prescribing information, please call 1-877-TARCEVA or visit <http://www.tarceva.com>.

Tarceva is co-developed in the United States by Genentech, Inc., a wholly owned member of the Roche Group, and OSI Pharmaceuticals, Inc., and is a trademark of OSI Pharmaceuticals, Inc., Melville, NY 11747, USA.

#### References

1. Tarceva [package insert]. Melville, NY: OSI Pharmaceuticals, Inc.; 2009.
2. National Comprehensive Cancer Network, Inc. Clinical Practice Guidelines in Oncology; Version 1.2009.
3. American Cancer Society. Cancer Facts & Figures 2008.  
<http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf>
4. Carter P, Presta L, Gorman CM, et al. Humanization Of An Anti-p185HER2 Antibody For Human Cancer Therapy. *Proc Natl Acad Sci*. 1992;89:4285-4289.
5. Prenzel N, Fischer OM, Streit S, Hart S, Ullrich A. The Epidermal Growth Factor Receptor Family As A Central Element For Cellular Signal Transduction And Diversification. *Endocrine-Related Cancer*. 2001;8:11-31.
6. Britten CD. Targeting ErbB Receptor Signaling: A Pan-ErbB Approach To Cancer. *Mol Cancer Ther*. 2004;3:1335-1342.

9228101