



FACT SHEET

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Tarceva (erlotinib) in Advanced Non-Small Cell Lung Cancer and Advanced Pancreatic Cancer

Tarceva[®] (erlotinib), a once-a-day pill, is approved for first-line maintenance therapy in people with advanced non-small cell lung cancer (NSCLC) whose cancer has not spread or grown after initial treatment with certain types of chemotherapy, and as a treatment for patients with advanced NSCLC who have progressed following treatment with at least one prior chemotherapy regimen (second/third-line). Tarceva is not intended to be used at the same time as chemotherapy for advanced NSCLC. Tarceva is also approved for the treatment of people with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed, and who have not received previous chemotherapy.

Tarceva was one of the first targeted treatments approved by the U.S. Food and Drug Administration (FDA) specifically designed to target the Epidermal Growth Factor Receptor (EGFR) pathway.

How Tarceva Works (Proposed Mechanism of Action)

- Tarceva works inside the tumor cell by inhibiting the tyrosine kinase activity of the EGFR pathway, which is one of the critical growth factors in NSCLC and pancreatic cancer.^{1,2}
- By blocking this activity, it is thought that Tarceva may help slow or stop the growth of tumors.³
- The way Tarceva works to treat cancer is not fully known.

Tarceva in Advanced Non-Small Cell Lung Cancer

First-Line Maintenance Therapy

The purpose of maintenance therapy is to provide active treatment in people whose tumors have stopped growing, before the cancer worsens. Once cancer grows or

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spreads, some people are unable to receive further treatment. Many times this is because the disease spreads rapidly and symptoms get worse.^{4,5}

In April 2010, Tarceva became the first oral maintenance therapy approved by the FDA for people with advanced NSCLC (both squamous and non-squamous). Tarceva is the only maintenance therapy approved for people with squamous NSCLC.

The approval of Tarceva as a first-line maintenance therapy was based on results of the pivotal Phase III SATURN clinical trial, which showed that Tarceva helped some people live longer, compared to placebo.³

- People treated with Tarceva had a 23 percent improvement in survival compared to placebo³
 - Hazard ratio=0.81 (95% CI: 0.70-0.95; p=0.0088)³
 - Median survival with Tarceva was 12.0 months vs. 11.0 months for placebo³

SATURN also showed that Tarceva increased the likelihood that a person would live longer without his or her tumor growing or spreading based on the investigator's assessment, a measure known as progression-free survival (PFS).³

- People treated with Tarceva had a 41 percent improvement in PFS compared to placebo³
 - Hazard ratio=0.71 (95% CI: 0.62-0.82; p<0.0001)³
 - Median PFS with Tarceva was 2.8 months vs. 2.6 months for placebo³

Second/Third-Line Therapy

Tarceva was approved by the FDA in November 2004 for people whose disease has worsened after receiving one or more courses of chemotherapy. This approval was based on results of the pivotal Phase III BR.21 clinical trial, which showed that Tarceva helped some people live longer, compared to placebo, regardless of the physical or genetic characteristics of their tumors.³

- People treated with Tarceva had a 37 percent improvement in survival compared to placebo³
 - Hazard ratio=0.73 (95% CI: 0.61-0.86; p<0.001)³
 - Median survival with Tarceva was 6.7 months vs. 4.7 months for placebo³
 - Thirty-one percent of people who received treatment with Tarceva survived at least one year, compared to 21.5 percent of people who were treated with placebo³

There have been 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.

Tarceva in Advanced Pancreatic Cancer

Tarceva, used in combination with gemcitabine chemotherapy, was approved by the FDA in November 2005 for the treatment of advanced pancreatic cancer in people who

have not received prior chemotherapy (first-line treatment). Tarceva was the first FDA-approved medicine in more than a decade for advanced pancreatic cancer, and it remains the only targeted therapy approved for this devastating disease with limited treatment options.

The approval of Tarceva for the treatment of advanced pancreatic cancer was based on the pivotal Phase III PA.3 clinical trial, which showed that some people with advanced pancreatic cancer who received Tarceva plus chemotherapy lived longer than those treated with chemotherapy alone.³

- People treated with Tarceva and chemotherapy had a 23 percent improvement in survival compared to those who received chemotherapy alone³
 - Hazard ratio=0.81 (95% CI: 0.68-0.97; p=0.028)³
 - Median survival with Tarceva plus chemotherapy was 6.4 months vs. 6.0 months with chemotherapy alone³
 - Twenty-four percent of people treated with Tarceva plus chemotherapy survived at least one year, compared to 19 percent of people treated with chemotherapy alone³

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Tarceva Development Program

Researchers continue to investigate the use of Tarceva in advanced NSCLC and other cancers.

Important Tarceva Safety Information

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Eye irritation and damage to the cornea have been reported in patients taking Tarceva. Bleeding and clotting problems, including gastrointestinal and non-gastrointestinal bleeding, have been reported in clinical studies. 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 NSCLC clinical studies. 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 being developed and commercialized by Astellas U.S. Holding Inc., a holding company owned by Astellas Pharma Inc., in partnership with Genentech in the United States, Chugai in Japan, and Roche in the rest of the world.

References

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