Fact Sheet

Tarceva® (erlotinib) tablets
in Non-Small Cell Lung Cancer

Tarceva® (erlotinib) tablets is the first medicine approved by the U.S. Food and Drug Administration (FDA) for the initial treatment for people with non-small cell lung cancer (NSCLC), whose cancer has spread to other parts of the body, that has certain types of Epidermal Growth Factor Receptor (EGFR) mutations as detected by an FDA-approved test (First-line treatment).

Tarceva is already approved for people with advanced-stage NSCLC whose cancer has not spread or grown after initial treatment with certain types of chemotherapy (Maintenance treatment). Tarceva is also approved for people with advanced-stage NSCLC whose cancer has spread or grown after receiving at least one chemotherapy regimen (Second/Third-line treatment).

FDA Approval History for Tarceva in NSCLC

2004

- Approved for the initial treatment for people with NSCLC, whose cancer has spread to other parts of the body, that has certain types of EGFR mutations as detected by an FDA-approved test

2010

- Approved for maintenance treatment of people whose locally advanced or metastatic NSCLC has not progressed after four cycles of platinum-based chemotherapy
- Only oral maintenance therapy approved for people with locally advanced or metastatic NSCLC

2013

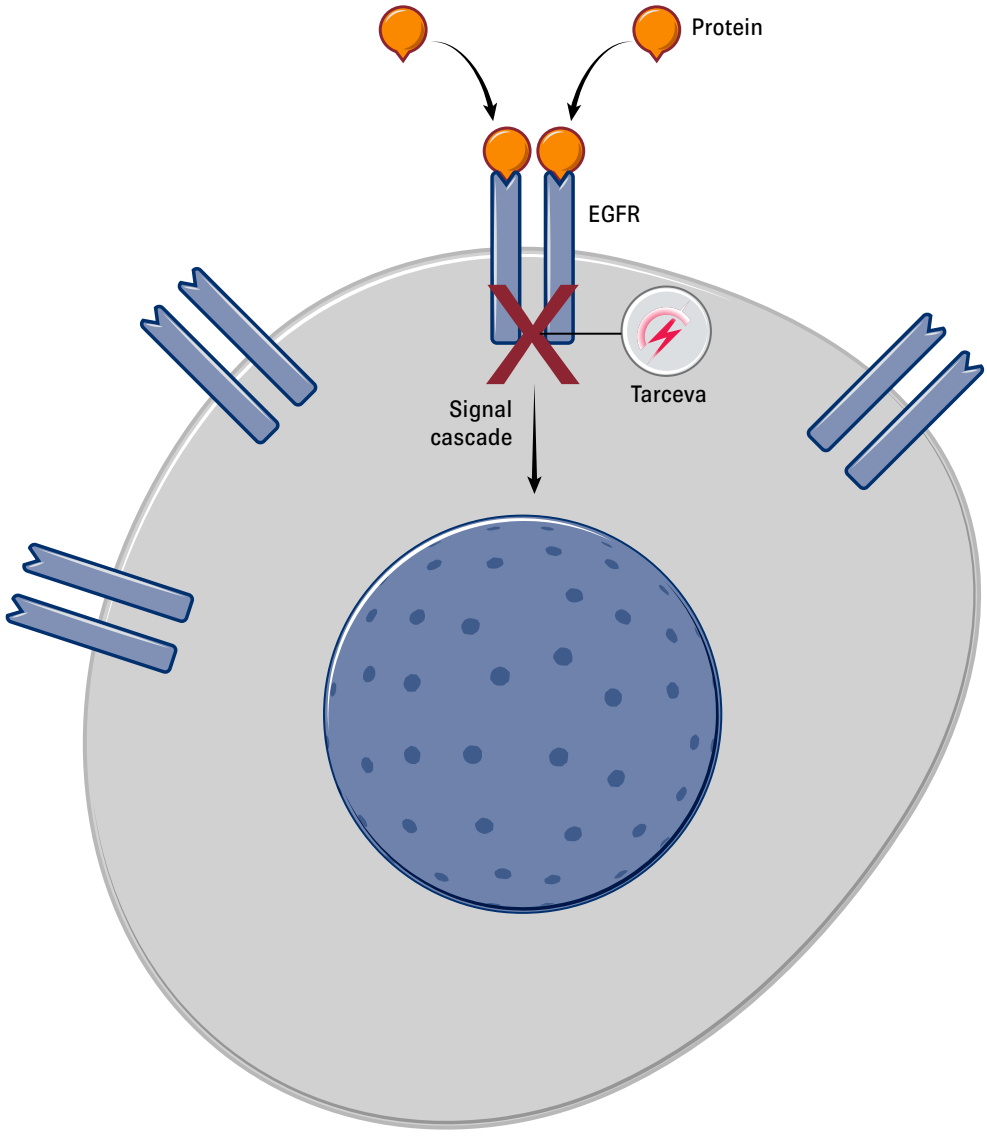
- Approved for the initial treatment for people with NSCLC, whose cancer has spread to other parts of the body, that has certain types of EGFR mutations as detected by an FDA-approved test
- Cobas® EGFR Mutation Test, developed by Roche, approved to confirm the status of people whose NSCLC tumors test positive for EGFR mutations
- First medicine specifically approved for the initial treatment of certain types of EGFR mutation-positive metastatic lung cancer

- Tarceva is not meant to be used at the same time as certain types of chemotherapy for advanced NSCLC.
- For initial treatment with NSCLC whose cancer has not spread to other parts of the body, it is not known if Tarceva is safe and effective in other EGFR mutations.

Please see the following pages and accompanying full Prescribing Information for Important Safety Information

- Genentech and Astellas continue to investigate Tarceva in clinical studies.
- Visit www.clinicaltrials.gov to find information about ongoing Tarceva clinical trials.
- Visit Genentech Access Solutions® (www.GenentechAccessSolutions.com) for coverage and reimbursement support, patient assistance and information resources.

The EGFR Pathway and Tarceva (Proposed Mechanism of Action)



1. Epidermal Growth Factor Receptors (EGFR) are expressed on the cell surface of both normal and cancer cells.

2. Tarceva attaches to EGFR, which are responsible for bringing signals into the cell that tell it to grow and divide.[1,2] These signals occur when certain proteins attach to EGFR.[2]

3. Tarceva works inside the cell by stopping EGFR signaling, even when mutations that keep EGFR locked in an active state are not present.[1]

4. By blocking EGFR activity, Tarceva may help slow or stop the growth of tumors.[1]

The way Tarceva works to treat cancer is not fully known.[1]

Tarceva Efficacy Profile in NSCLC

First-Line Treatment

Tarceva **demonstrated a significant improvement in progression-free survival** (HR=0.34, 95% CI: 0.23-0.49; p<0.001)

EURTAC Study	Tarceva N=86	Chemotherapy N=88
Median progression-free survival (mPFS)	10.4 months	5.2 months

Second-Line/Third-Line Treatment

Tarceva **reduced the risk of death by 27 percent** (HR=0.73, 95% CI: 0.61-0.86; p<0.001)

BR.21 Study	Tarceva N=488	Placebo N=243
Median overall survival (mOS)	6.7 months	4.7 months
mPFS*	2.3 months	1.8 months

*HR=0.59, 95% CI: 0.50-0.70; p<0.001

Maintenance Treatment

Tarceva **reduced the risk of progression or death by 29 percent** (HR=0.71, 95% CI: 0.62-0.82; p<0.0001)

SATURN Study	Tarceva N=438	Placebo N=451
mPFS	2.8 months	2.6 months
mOS*	12.0 months	11.0 months

*HR=0.81, 95% CI: 0.70-0.95; p=0.0088

First-Line Treatment: EURTAC Study

The approval of Tarceva for initial (first-line) treatment of patients with metastatic NSCLC whose tumors have certain types of EGFR activating mutations, as detected by an FDA-approved test, was based upon the results of the EURTAC study, a Phase III randomized, prospective, open-label study that evaluated the first-line use of Tarceva versus platinum-based chemotherapy in 174 people with EGFR mutation-positive (exon 19 deletions or exon 21 [L858R] substitution mutations) metastatic NSCLC.

Second-Line/Third-Line Treatment: BR.21 Study

The approval of Tarceva for second- and third-line treatment was based upon results of the BR.21 study, a Phase III randomized, double-blind, placebo-controlled trial that evaluated Tarceva compared to placebo in 731 people with locally advanced or metastatic NSCLC who had progressed after failure of at least one chemotherapy regimen.

Maintenance Treatment: SATURN Study

The approval of Tarceva for maintenance treatment was based upon the results of the SATURN study, a Phase III randomized, double-blind, placebo-controlled study that evaluated Tarceva compared to placebo in 889 people with locally advanced or metastatic NSCLC whose disease did not progress during first-line platinum-based chemotherapy.

Select Important Safety Information

Warnings and precautions, which may include fatalities, associated with Tarceva in advanced NSCLC include interstitial lung disease (ILD), renal failure, hepatotoxicity with or without hepatic impairment, gastrointestinal perforation, bullous and exfoliative skin disorders, myocardial infarction/ischemia, cerebrovascular accident, microangiopathic hemolytic anemia with thrombocytopenia, ocular disorders, hemorrhage in patients taking warfarin, embryo-fetal toxicity.

References

1. Tarceva [package insert]. Farmingdale, NY: OSI Pharmaceuticals, LLC, an affiliate of Astellas Pharma US, Inc.; 2013.
2. Prenzel N, Fischer OM, Streit S, Hart S and Ullrich A. The Epidermal Growth Factor Receptor as a Central Element for Cellular Signal Transduction and Diversification. *Endocr Relat Cancer.* 2008;2001:11-31.

Important Safety Information

Everyone reacts differently to Tarceva therapy. So it's important to know what the side effects are. Your healthcare provider (HCP) may reduce or stop treatment if any serious side effects occur. Be sure to contact your healthcare team if you have the following symptoms related to these side effects.

What is the most important information I should know about Tarceva?

- **Interstitial lung disease (ILD)-like events.** Problems occurring in the lungs (including deaths). Tarceva may need to be stopped if new or unexplained serious symptoms of shortness of breath, cough, and fever occur.
- **Liver and/or kidney problems.** Some events have included death. Let your healthcare provider (HCP) know if you have a history of liver or kidney disease.
- **Gastrointestinal (GI) perforation.** A hole that develops in your stomach or intestine. Some events have included death.
- **Serious skin conditions.** Some events have included death.
- **Bleeding and clotting problems.** Heart attack or stroke in patients receiving Tarceva plus gemcitabine for advanced pancreatic cancer.
- **Eye disorders.** Eye irritation and damage to the cornea.
- **Bleeding events when taking warfarin.** Some events have included death. Tell your doctor if you are taking warfarin or non-steroidal anti-inflammatory drugs (NSAIDs).
- **Pregnancy.** In pregnant women, Tarceva can cause harm to the fetus. Do not breast-feed when taking Tarceva. Women should use highly effective contraception during therapy and at least 2 weeks after the last dose of Tarceva. Contact your HCP immediately if you become pregnant.

Call your HCP right away for:

- Serious or ongoing diarrhea, nausea, loss of appetite, or vomiting
- New or worsening of unexplained shortness of breath or cough
- Eye irritation
- New or worsening skin rash or blistering or skin peeling
- Any changes in smoking habits

The most common, but less serious side effects include:

- First line NSCLC treatment: Diarrhea, weakness, rash, cough, shortness of breath, and loss of appetite.
- Maintenance/ Second- or Third-Line NSCLC treatment: Rash and diarrhea.

It is important that you tell your HCP about all of the medicines and herbal supplements you are taking:

- DO NOT start taking any new medicines or herbal supplements before talking with your HCP.
- DO NOT eat grapefruit or drink grapefruit juice while on treatment with Tarceva, except under the care of your HCP.

Smoking may affect how well Tarceva works for you.

- If you smoke, you should stop smoking before starting treatment with Tarceva.
- If you continue to smoke, you should talk to your HCP before taking Tarceva.

Always let your HCP know if you have any side effects, and ask about the best way to handle them.

Tarceva is not right for everyone. Ask your HCP if once-daily Tarceva is right for you.

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

For full prescribing information including other important safety information for Tarceva, please visit www.Tarceva.com.

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