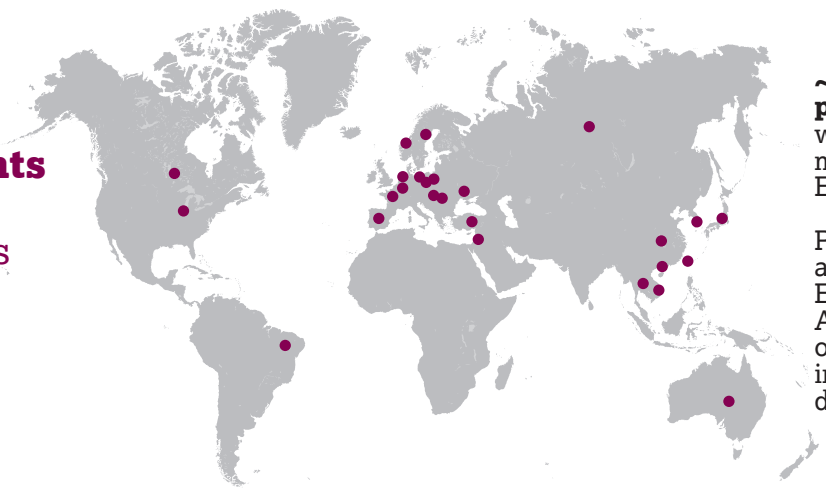
TAGRISSO® (OSIMERTINIB) IN THE ADJUVANT TREATMENT OF PATIENTS WITH EGFR-MUTATED NON-SMALL CELL LUNG CANCER FOLLOWING SURGERY

ABOUT THE ADAURA PHASE III TRIAL

The first global Phase III trial of an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) to show statistically significant and clinically meaningful improvement in disease-free survival (DFS) in patients with resectable Stage IB-IIIA EGFRm Non-Small Cell Lung Cancer (NSCLC).[1]

The ADAURA data were released 2 years early after a recommendation from an Independent Data Monitoring Committee, based on its determination of overwhelming efficacy. The ADAURA trial continues to assess overall survival, and investigators and patients who are currently being followed remain blinded to which treatment they are receiving — TAGRISSO or placebo.[1]

The ADAURA trial **enrolled 682 patients** in more than **200 centers** across more than **20 countries**.[1, 2]



~70% of enrolled patients were women, who are more likely than men to be diagnosed with EGFRm NSCLC.[3-7]

Patients were enrolled at multiple sites across Eastern and Southeastern Asia, ensuring representation of the population most impacted by this devastating disease.[2]

RANDOMIZED TRIAL DESIGN

682 patients
with Stage IB-IIIA EGFRm NSCLC who had their tumor completely removed by surgery with or without adjuvant chemotherapy[1]

339 patients
received TAGRISSO 80 mg once-daily oral tablets

343 patients
received placebo

...for three years until disease recurrence, treatment completion, or trial discontinuation[1]

RESULTS

Adjuvant treatment with TAGRISSO reduced the risk of disease recurrence or death[1]

Primary Endpoint:

In the ADAURA clinical trial, Stage II and IIIA EGFRm NSCLC patients treated with TAGRISSO following surgery were 83% less likely to experience cancer recurrence or death than with placebo.[1]

83%

Key Secondary Endpoint:

Patients in the overall trial population (Stage IB, II, and IIIA) treated with TAGRISSO following surgery were 80% less likely to experience cancer recurrence or death than with placebo.[1]

80%

The safety and tolerability of TAGRISSO in the ADAURA trial were consistent with the established safety profile.[1]

TAGRISSO IMPORTANT SAFETY INFORMATION

TAGRISSO may cause serious side effects, including:

- **lung problems.** TAGRISSO may cause lung problems that may lead to death. Symptoms may be similar to symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening lung symptoms, including trouble breathing, shortness of breath, cough, or fever
- **heart problems, including heart failure.** TAGRISSO may cause heart problems that may lead to death. Your healthcare provider should check your heart function before you start taking TAGRISSO and during treatment as needed. Tell your healthcare provider right away if you have any of the following signs and symptoms of a heart problem: feeling like your heart is pounding or racing, shortness of breath, swelling of your ankles and feet, feeling lightheaded
- **eye problems.** TAGRISSO may cause eye problems. Tell your healthcare provider right away if you have symptoms of eye problems which may include watery eyes, sensitivity to light, eye pain, eye redness, or vision changes. Your healthcare provider may send you to see an eye specialist (ophthalmologist) if you get eye problems with TAGRISSO
- **skin problems.** TAGRISSO may cause skin problems. Tell your healthcare provider right away if you develop target lesions (skin reactions that look like rings), severe blistering or peeling of the skin
- **inflammation of the blood vessels in your skin.** TAGRISSO may cause blood vessel problems in your skin. Tell your healthcare provider right away if you develop purple spots or redness of the skin that does not fade in color when pressed (non-blanching) on your lower arms, lower legs, or buttocks or large hives on the main part of your body (trunk) that do not go away within 24 hours and look bruised

Before taking TAGRISSO, tell your healthcare provider about all of your medical conditions, including if you:

- have lung or breathing problems
- have heart problems, including a condition called long QTc syndrome
- have problems with your electrolytes, such as sodium, potassium, calcium or magnesium
- have a history of eye problems
- are pregnant or plan to become pregnant. TAGRISSO can harm your unborn baby. Tell your healthcare provider right away if you become pregnant during treatment with TAGRISSO or think you may be pregnant
  - Females who are able to become pregnant should have a pregnancy test before starting treatment with TAGRISSO. You should use effective birth control during treatment with TAGRISSO and for 6 weeks after the final dose of TAGRISSO
  - Males who have female partners that are able to become pregnant should use effective birth control during treatment with TAGRISSO and for 4 months after the final dose of TAGRISSO
- are breastfeeding or plan to breastfeed. It is not known if TAGRISSO passes into your breast milk. Do not breastfeed during treatment with TAGRISSO and for 2 weeks after your final dose of TAGRISSO. Talk to your healthcare provider about the best way to feed your baby during this time

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. Especially tell your healthcare provider if you take a heart or blood pressure medicine

The most common side effects of TAGRISSO are:

- low white blood cell counts
- low platelet counts
- diarrhea
- low red blood cell counts (anemia)
- rash
- changes in your nails, including: redness, tenderness, pain, inflammation, brittleness, separation from nailbed, and shedding of nail
- dry skin
- mouth sores
- tiredness
- cough
- muscle, bone, or joint pain

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TAGRISSO. For more information, ask your healthcare provider or pharmacist.
Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What is TAGRISSO?

TAGRISSO is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC) that has certain abnormal epidermal growth factor receptor (EGFR) gene(s):

- to help prevent your lung cancer from coming back after your tumor(s) has been removed by surgery, **or**
- as your first treatment when your lung cancer has spread to other parts of the body (metastatic), **or**
- when your lung cancer has spread to other parts of the body (metastatic) and you have had previous treatment with an EGFR tyrosine kinase inhibitor (TKI) medicine that did not work or is no longer working

Your healthcare provider will perform a test to make sure that TAGRISSO is right for you.
It is not known if TAGRISSO is safe and effective in children.

Please see complete Prescribing Information, including Patient Information.

REFERENCES

1. Wu YL, et al. Osimertinib in Resected *EGFR*-Mutated Non–Small-Cell Lung Cancer. *N Engl J Med*. 2020;383(18):1711-1723.
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6. Zhang YL, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. *Oncotarget*. 2016;7(48):78985–78993.
7. Bell D, et al. Increased Prevalence of EGFR-Mutant Lung Cancer in Women and in East Asian Populations: Analysis of Estrogen-Related Polymorphisms. *Clin Cancer Res. 2008*;14(13):4079-4084.

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