

# **OSCILLATE – Phase 2 trial of alternating osimertinib with gefitinib in patients with EGFR-T790M mutation positive advanced non-small cell lung cancer**

Protocol number: CTC 0152 / TOGA 16/005

---

This is a short summary of the results from this trial of treatments for a particular type of lung cancer. We designed the OSCILLATE trial to learn if it might be better to switch back and forth between two drugs, osimertinib and gefitinib, rather than using osimertinib on its own in this particular type of lung cancer. We thank the 47 people who took part in the trial, their families, doctors, and others who helped run it at 14 hospitals throughout Australia. Their contributions have helped us learn more about options to treat this condition.

## **What was the trial about?**

About 1 in 6 Australians with lung cancer have a changed gene (mutation) for the epidermal growth factor receptor (EGFR). This mutation in the EGFR gene makes this particular cancer grow. To specifically target the effects of this mutation, standard treatments include drugs like gefitinib and osimertinib. These drugs are often effective for a period of time, but then stop working and the lung cancer becomes less sensitive to the drug. This is called drug resistance. Laboratory studies suggested that switching the two drugs gefitinib and osimertinib back and forth (alternating treatment) may delay the development of drug resistance.

The primary outcome of the trial was the proportion of people whose cancer remained under control at 12 months (progression-free survival at 12 months). Other outcomes measured were the feasibility of this treatment approach, the proportion of people whose cancer had shrunk in response to treatment (tumour response rate), and safety. The study also included research into circulating tumour DNA levels and mechanisms of resistance.

## **How well did alternating treatment work?**

The results of alternating treatment in OSCILLATE were similar to those in other trials of osimertinib alone. 68% of people in OSCILLATE were able to complete 6 months of treatment without any delays or interruptions due to side effects, suggesting that the alternating approach was safe and feasible. The lung cancer was still under control 12 months after starting treatment in 38% of the participants.

## **What were the side-effects of the treatment?**

The side effects of treatment in OSCILLATE were similar to those seen in trials using either drug on its own. These side effects included skin rash, nail changes, diarrhoea, and stomach upsets in some people. Serious side effects were rare.

## **How will the results help patients and doctors in future?**

OSCILLATE showed that it was possible and safe to alternate osimertinib and gefitinib, and that the outcomes were similar to those using osimertinib alone. Further studies are needed to identify those people who might benefit more from alternating two drugs rather than using osimertinib alone.

## **What are the researchers going to do next?**

We will study blood samples taken during the trial to learn more about how the study drugs work, and which people might stand to benefit most from alternating treatment.

## **What does this mean for me?**

The results of any single research study do not represent complete knowledge about treatments. Therefore, people should not change their treatment based on the results of this study alone. If you have any questions, please talk to your doctor.

## **Where can I find out more about the trial?**

More details about the trial are available on:

- NHMRC Clinical Trials Centre website at <https://ctc.usyd.edu.au/our-work/research-divisions/cancer/cancer-divisions/lung-cancers/in-follow-up/OSCILLATE/>
- Australian and New Zealand Cancer Trials registry at <http://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=372967&isReview=true>
- Thoracic Oncology Group of Australasia (TOGA) website at <https://thoraciconcology.org.au/clinical-trials/>

## **Sponsor, funding and conflicts of interest**

This study was led and run by the NHMRC Clinical Trials Centre in collaboration with the Australasian Lung cancer Trials Group (ALTG)/Thoracic Oncology Group of Australasia (TOGA). The trial was sponsored by the University of Sydney. Gefitinib, osimertinib, and funds to help run the trial, were provided by Astra Zeneca.