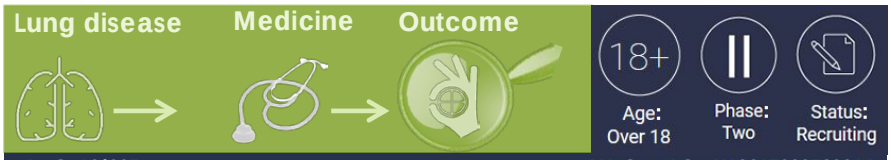
Trial Information Summary - OSCILLATE

OSCILLATE - Phase II trial to determine the efficacy, safety, and feasibility of alternating osimertinib with gefitinib in patients with EGFR-T790M mutation positive advanced non-small cell lung cancer (NSCLC).



The information contained in this document is intended for discussion with your health professional to help determine your potential eligibility.

It is hoped that the findings from this trial will provide information on whether alternating treatment with osimertinib and gefitinib is feasible, safe and effective for the treatment of EGFR-T790M mutation positive advanced non-small cell lung cancer (NSCLC).

Inclusions

- Adults, aged 18 years and older, with histologically or cytologically confirmed metastatic or unresectable locally advanced NSCLC;
- Prior therapy with an EGFR-TKI. Patients may also have received additional lines of treatment;
- Documented evidence of EGFR-T790M mutation on tissue and/or plasma sample following disease progression on the most recent EGFR-TKI therapy (T790M mutation status will need to be re-confirmed in the event of an alternative systemic treatment following progression on the most-recent EGFR-TKI therapy);
- Measurable disease according to RECIST version 1.1;
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2.

Exclusions

- Previous or current treatment with osimertinib or other drugs that target EGFR-T790M mutations, e.g. CO-1686, HM61713, TAS-121;
- Contraindications to investigational product;
- Any unresolved toxicity from prior therapy worse than CTCAE grade 1, except alopecia and grade 2 neuropathy due to prior platinum-based chemotherapy;
- Major surgery within 4 weeks, or palliative radiation therapy within 5 days before enrolment;
- Treatment with prohibited medications (e.g. concurrent anti-cancer therapy including other chemotherapy, or immunotherapy within 14 days prior to treatment);
- Patients currently receiving (or unable to stop at least 1 week before starting osimertinib) potent inhibitors or inducers of cytochrome P450 (CYP) 3A4;
- Patient with symptomatic central nervous system (CNS) metastases, neurologically unstable, or require increasing doses of steroids to manage CNS symptoms within 2 weeks prior to starting osimertinib. Patients with leptomeningeal carcinomatosis;
- Known history of interstitial lung disease
- Life expectancy of less than 3 months
- Mean QT interval corrected for heart rate (QTc) > = 470 ms OR any clinically important abnormalities in rhythm, conduction or morphology of resting ECG OR any factors that increases the risk of QTc prolongation or risk of arrhythmic events.

This is a summary document of the inclusion and exclusion criteria of the study.
Please contact your oncologist or GP to discuss the full details of this trial.

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Participating sites

State	Site
NSW	Calvary Mater Newcastle
	Liverpool Hospital - Liverpool
	St Vincent's Hospital (Darlinghurst)
	Concord Repatriation Hospital
	St George Hospital
	The Chris O'Brien Lifehouse
	Gosford Hospital - Gosford
	Royal North Shore Hospital - St Leonards
VIC	Peter MacCallum Cancer Centre
	St Vincent's Hospital
	Monash Medical Centre - Clayton campus - Clayton