Trial Information Summary - ILLUMINATE

ILLUMINATE - Phase II, single arm trial to assess the efficacy and tolerability for patients with the use of Durvalumab and Tremelimumab with Chemotherapy in metastatic EGFR non-small cell lung cancer (NSCLC) following progression on EGFR tyrosine kinase inhibitors.

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

The findings from this trial will provide information on the tolerability and effectiveness of combining Durvalumab and Tremelimumab with Chemotherapy in patients with metastatic EGFR non-small cell lung cancer (NSCLC) after they have progressed on EGFR Tyrosine Kinase Inhibitors.

Inclusions Criteria – summary only

- Adults, aged 18 years and older, with histologically or cytologically confirmed Non-Small Cell Lung Cancer (NSCLC) with EGFR mutation;
- Disease that has progressed and either

  (i) No evidence of EGFR T790M resistance mutation in both tissue re-biopsy & plasma after one-line of EGFR TKI therapy

  (ii) T790M mutation (detection in tissue re-biopsy, plasma or both) and progression on 3rd generation EGFR TKI. Patients are allowed to have one prior line of TKI therapy prior to 3rd generation TKI therapy
- Co-mutations are eligible provided one mutation is either Exon 19 deletion or Exon 21 L858R point mutation
- Provision of pre-treatment tumour tissue sample from a biopsy taken within 42 days prior to enrolment (core biopsy preferred) to determine NSCLC histology and for translational research
- Measurable disease (RECIST1.1)
- Eastern Cooperative Oncology Group (ECOG) performance status 0-1;
- Adequate haematological, renal, hepatic blood tests (check for details);
- Post-menopausal or negative pregnancy test for females of child-bearing potential

Exclusion Criteria – summary only – NOT ALL LISTED

- Prior chemotherapy or immunotherapy, including prior anti PD-1/anti PD L1 or anti CTLA-4 antibodies for advanced NSCLC
- Prior adjuvant chemotherapy or concurrent chemo/radiotherapy with curative intent is allowed but must have completed more than 6 months prior to start of trial and must not have included treatment with an immune checkpoint inhibitor
- Prior EGFR TKI (eg erlotinib, gefitinib, afatinib or osimertinib) including experimental TKI agents within 8 days or approx. 5 x half-life, whichever is longer of the first dose of the study treatment is allowed.
- Untreated CNS metastases – patients with brain metastases that have been treated may participate provide they show radiographic stability
- Mixed histology with any small cell or squamous component
- Life expectancy of less than 3 months
- Current enrolment or participation in another clinical study with an investigational product during the past 12 months unless it is non-interventional
- Any unresolved toxicity equal to or greater than grade 2 (grade 2 peripheral neuropathy will be evaluated on a case by case basis). Check for other toxicity details
- Radiotherapy or major surgery within 4 weeks of first dose of study drug
- History of pneumonitis, pulmonary fibrosis, active immunodeficiency or allogenic transplant
- Active or prior autoimmune disorders – see ANZCTR for details
- Concurrent illnesses
- History of other primary malignancies

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	St George Hospital - Kogarah
	Northern Cancer Institute – St Leonards
	Liverpool Hospital – Liverpool
	Bankstown-Lidcombe Hospital – Bankstown
	Gosford Hospital - Gosford
Vic	Peter MacCallum Cancer Centre - Melbourne
	Monash Medical Centre – Clayton Campus - Clayton
	St Vincent's Hospital (Melbourne) – Fitzroy
SA	Flinders Medical Centre – Bedford Park
QLD	The Prince Charles Hospital – Chermside
	Princess Alexandra Hospital – Woolloongabba
WA	Sir Charles Gardiner Hospital – Nedlands
Tas	Royal Hobart Hospital - Hobart