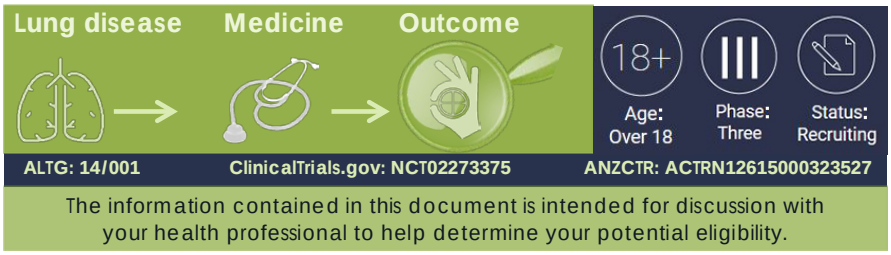
Trial Information Summary - BR.31

BR.31 - A phase III prospective double-blind placebo-controlled randomized study of adjuvant MEDI4736 in completely resected 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.

This study looks at the effectiveness of adjuvant therapy with MEDI4736 in patients with completely resected non-small cell lung cancer (NSCLC). MEDI4736 is a human monoclonal antibody directed against programmed cell death ligand 1 (PD-L1). Signals from PD-L1 help tumours avoid detection by the immune system. MEDI4736 blocks these signals, countering the tumour's immune-evading tactics.

Inclusions

- Histologically confirmed diagnosis of primary non-small cell carcinoma of the lung. Patients with large-cell neuroendocrine carcinomas are not eligible;
- Patients must be classified post-operatively as Stage IB (> 4cm in the longest diameter), II or IIIA on the basis of pathologic criteria. Complete surgical resection of the primary NSCLC is mandatory (negative margins);
- Pre-operative (neo-adjuvant) platinum based or other chemotherapy is not permissible. Patients may have received prior post-operative platinum based chemotherapy as per standard of care;
- No prior anticancer therapy for treatment of NSCLC other than standard post-operative adjuvant chemotherapy is permissible;
- Patients with N2 disease only who receive adjuvant post-operative radiation therapy are eligible provided they meet the protocol specified timing criteria for surgery, adjuvant chemotherapy and randomization;
- Hematology: Absolute neutrophil count ≥ 1.5 x 109/L or ≥ 1,500/µl Platelets ≥ 100 x 109/L or ≥ 100,000/µl;
- Biochemistry: Total bilirubin ≤ institutional upper limit of normal Alkaline phosphatase ≤ 2.5 x institutional upper limit of normal AST(SGOT) and ALT(SGPT) ≤ 2.5 x institutional upper limit of normal Creatinine Clearance ≥ 40 ml/min;
- Patient able and willing to complete the QoL, economics and other questionnaires;
- Patient consent must be appropriately obtained in accordance with applicable local and regulatory requirements;
- Patients must be accessible for treatment, follow-up;
- Protocol treatment is to begin within 2 working days of patient randomization.

Exclusions

- Patients with a history of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer, or other solid tumours curatively treated with no evidence of disease for > 5 years following the end of treatment;
- A combination of small cell and non-small cell lung cancer or pulmonary carcinoid tumour;
- History of autoimmune disease;
- History of primary immunodeficiency, history of allogenic organ transplant that requires therapeutic immunosuppression and the use of immunosuppressive agents within 28 days of randomization;
- Live attenuated vaccination administered within 30 days prior to randomization;
- History of hypersensitivity to MEDI4736 or any excipient;
- Patients who have experienced untreated and/or uncontrolled cardiovascular conditions and/or have symptomatic cardiac dysfunction;
- Concurrent treatment with other investigational drugs or anti-cancer therapy;
- Patients with active or uncontrolled infections or with serious illnesses or medical conditions which would not permit the patient to be managed according to the protocol;
- Pregnant or lactating women.

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.

NHMRC Clinical Trial Coordinator
BR.31@ctc.usyd.edu.au

ALTG Program Manager
altg@lungfoundation.com.au

Participating sites

State	Site
ACT	Canberra Hospital
NSW	Border Medical Oncology
	Campbelltown Hospital
	Central Coast Cancer Centre
	Chris O'Brien Lifehouse
	Coffs Harbour Health Campus - NCCI
	Liverpool Hospital
	Nepean Cancer Care Centre
	Northern Cancer Institute, St Leonards
	St George Hospital
	Westmead Hospital
QLD	Mater Adult Hospital Brisbane
	Nambour General Hospital
	Princess Alexandra Hospital
	The Prince Charles Hospital
SA	Flinders Medical Centre
	Royal Adelaide Hospital
TAS	Royal Hobart Hospital
VIC	Austin Hospital
	Epworth Richmond Hospital
	Monash Medical Centre
	Peninsula Oncology Centre, Frankston
	Royal Melbourne Hospital, Parkville
	St Vincent's Hospital Melbourne and St Vincent's Hospital Private Hospital
WA	Fiona Stanley Hospital
	Sir Charles Gairdner Hospital
NZ	Canterbury Regional Cancer and Haematology Service