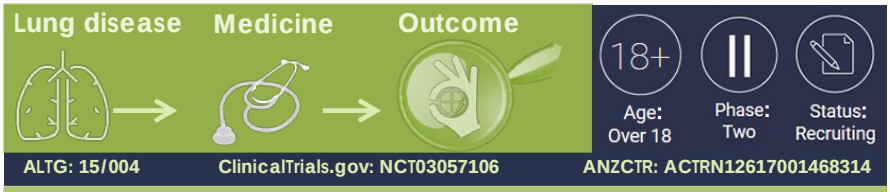
Trial Information Summary - BR.34

BR.34 - A randomized trial of durvalumab and tremelimumab +/- platinum-based chemotherapy in patients with high-risk, metastatic (stage IV) squamous or non-squamous 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.

The purpose of this study is to compare the effects of an immunotherapy combination of both durvalumab plus tremelimumab with or without chemotherapy on you and your lung cancer.

Inclusions

- Patients must have histologically and/or cytologically confirmed diagnosis of squamous or non-squamous, non-small cell carcinoma of the lung. Patients with poorly differentiated tumours will only be eligible if NSCLC is confirmed by immunohistochemistry markers (TTF1/P63 or P40/CK5);
- Patients must be high risk, defined as the presence of one or more of the following unfavourable prognostic factors: Stage IVB disease, Stage IVA disease with at least one of the following: Elevated LDH, Weight loss ≥ 5% over 3 months before randomization, Poorly differentiated histology;
- Patients must have an adequate histopathology specimen and consent to release this specimen for protocol required testing;
- Patients must have measurable disease as defined by RECIST 1.1;
- ECOG performance status of 0 or 1, Absolute neutrophils ≥ 1.5 x 10^9/L, Platelets ≥ 100 x 10^9/L, Hemoglobin ≥ 90 g/L,Bilirubin ≤ 1.5 x UNL, AST and ALT ≤ 2.5 x UNL, Creatinine < 1.25 UNL or Creatinine clearance ≥ 45 mL/min;
- Patients may not have received prior cytotoxic chemotherapy for advanced/metastatic disease. Patients may have had prior adjuvant therapy for completely resected disease, providing it has been completed at least 12 months prior to randomization. Patients treated with concurrent chemotherapy/radiation regimens for unresectable locally advanced Stage III disease will be eligible providing it has been completed at least 12 months prior to randomization. Patients may not have received prior treatment with immune-based therapy, including durvalumab and tremelimumab vaccines or oncolytic viral therapy;
- Prior external beam radiation is permitted provided a minimum of 14 days have elapsed between the last dose of radiation and date of randomization. Concurrent radiotherapy is not permitted;
- Patients must have recovered from any acute toxic effects from radiation prior to randomization;
- Female patients of childbearing potential who are sexually active with a non-sterilized male partner must use at least one highly effective method of contraception while on study and for 6 months after the last dose of durvalumab and tremelimumab or for 3 months after the last dose of durvalumab alone.

Exclusions

- Patients with a history of other malignancies, except: adequately treated non-melanoma skin cancer, curatively treated in-situ cancer of the cervix, or other solid tumours curatively treated with no evidence of disease for ≥ 3 years;
- Active or prior documented autoimmune or inflammatory disorders, systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome, rheumatoid arthritis, hypophysis, uveitis, within the past 3 years prior to the start of treatment. The following are exceptions: Patients with alopecia, Grave's disease, vitiligo or psoriasis not requiring systemic treatment (within the last 2 years), and hypothyroidism stable on hormone replacement;
- History of primary immunodeficiency, 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 durvalumab or tremelimumab or any excipient;
- Mean QT interval corrected for heart rate using Fridericia's formula (QTcF) ≥ 470 msec or history of familial long QT syndrome;
- Patients who have untreated, uncontrolled cardiovascular conditions or symptomatic cardiac dysfunction;
- Concurrent treatment with other investigational drugs or anti-cancer therapy;
- Patients with untreated brain or meningeal metastases are not eligible. Patients with treated CNS disease who have radiologic and clinical evidence of stable brain metastases are eligible;
- Pregnant or Lactating Women: Women of childbearing potential must have a pregnancy test proven negative within 14 days prior to randomization;
- Patients with serious illnesses or medical conditions which would not permit the patient to be managed according to the protocol or would put the patient at risk.

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

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Participating sites

State	Site
NSW	Campbelltown Hospital
	Coffs Habour Health Campus - NCCI
	Concord Repatriation General Hospital
	Nepean Hospital
	St. George Hospital, Cancer Care Centre
	The Tweed Hospital
	Liverpool Cancer Therapy Centre
QLD	The Prince Charles Hospital
	Mater Research Institute South Brisbane
	Gold Coast University Hospital
	Toowoomba Hospital
TAS	Royal Hobart Hospital
VIC	Ballarat Health Services
	Border Medical Oncology
	St. Vincent's Hospital