Cancer Council Victoria | Victorian Cancer Trials Link

# Phase 3, Two-stage, Randomized Study of ONC-392 Versus Docetaxel in Metastatic Non-Small Cell Lung Cancers That Progressed on PD-1/PD-L1 Inhibitors

## Clinical summary

This study is comparing Gotistobart, an anti-CTLA-4 antibody, with Docetaxel chemotherapy in people with metastatic non-small cell lung cancer who have progressed on prior treatment with anti-PD-1/PD-L1 inhibitors.
This is a seamless 2-stage, randomised trial that will enroll approximately 600 patients.
Two Gotistobart dosing regimens will be tested in Stage 1, and one will be selected for Stage II.
Gotistobart will be administered through IV infusion over 60 minutes once every 21 days.
Stage I, the dose-confirmation stage, will assess the efficacy and safety of two Gotistobart dosing regimens (3mg/kg and 6mg/kg with 2 loading doses of 10mg/kg) in comparison to Docetaxel (IV infusion 75mg/m2) every 21 days.
Stage II will assess the safety and efficacy of Gotistobart at the selected dosing regimen versus Docetaxel. Participants will be radnomised 1:1 to receive either Gotistobart at the selected dosing regimen or Docetaxel.

## Conditions

This trial is treating patients with metastatic non-small cell lung cancer

**Trial Acronym**
PRESERVE-003

**Trial Identifiers**
NCT05671510

**Cancer**
Non-Small Cell Lung Cancer

**Age:** 18+
**Phase:** III

**For full trial details, visit trials.cancervic.org.au/details/vctl_nct05671510**