BEAT (ETOP)

A multicentre randomized phase III trial comparing atezolizumab plus bevacizumab and standard chemotherapy versus bevacizumab and standard chemotherapy as first-line treatment for advanced malignant pleural mesothelioma.

This is the trial summary as assessed on clinicaltrials.gov on 02/01/2020.

Minor changes in the protocol may occur. You can check this on this direct link:

https://clinicaltrials.gov/ct2/show/NCT03762018?term=ETOP+13-18+BEAT-meso&draw=2&rank=1

Trial Design:

The aim of this clinical trial is to assess the effect of treatment with a monoclonal antibody called atezolizumab in patients diagnosed with a type of lung cancer called malignant pleural mesothelioma. The efficacy (whether the treatment works), safety and tolerability (side effects of treatment) of atezolizumab plus bevacizumab in combination with standard chemotherapy versus bevacizumab in combination with standard chemotherapy will be investigated.

Participants will be randomly assigned to one of two treatment groups:

Treatment 1
- Bevacizumab 15 mg/kg intravenously on day 1 of every 3-week cycle, plus
- 4-6 cycles of chemotherapy

OR

Treatment 2
- Atezolizumab 1200 mg fixed dose intravenously on day 1 of every 3-week cycle, plus
- Bevacizumab 15 mg/kg, intravenously on day 1 of every 3-week cycle, plus
- 4-6 cycles of chemotherapy

Key Inclusion Criteria:

Histologically confirmed advanced malignant pleural mesothelioma (all histological subtypes are eligible)

Not amenable for radical surgery based on local standards

Evaluable disease or measurable disease as assessed according to the modified response evaluation criteria for solid tumors for mesothelioma (mRECIST) v1.1

Availability of tumor tissue for translational research

Age >18 years

Performance Status 0-1

Life expectancy >3 months

Adequate hematological, renal and liver function

Completed baseline quality of life (QoL) questionnaire

Women of childbearing potential and sexually active men must agree to use highly effective contraception

Able to understand and give written informed consent and comply with trial procedures

Key Exclusion Criteria:

Prior treatment for malignant pleural mesothelioma

Treatment with systemic immune-stimulatory agents within 4 weeks or five half-lives of the drug prior to randomization and during protocol treatment.

Treatment with systemic immunosuppressive medications within 2 weeks prior to randomization and during protocol treatment.

Previous allogeneic tissue/solid organ transplant

Live vaccines within 4 weeks prior to first dose of protocol treatment

Inadequately controlled hypertension

Prior history of hypertensive crisis or hypertensive encephalopathy

Significant vascular disease within 6 months prior to randomization

History of haemoptysis