Sasanlimab (Pfizer)

This is a study for people with advanced (stage 3b or 4) NSCLC. The purpose of this study is to learn if the study medicine (sasanlimab, a PD-1 antagonist monoclonal antibody) along with other study medicines is safe and effective in people with NSCLC that has spread outside of the lungs.

People in the second sub-study (B) will receive the study medicine sasanlimab as a subcutaneous (under the skin) injection at the study clinic every 3 weeks and will also receive SEA-TGT (an immunotherapy) by infusion every three weeks. Additionally, they will take axitinib (a targeted therapy) by mouth twice a day at home. **Sub-study (A) is not active in UZ Leuven!**

This is the trial summary as assessed on clinicaltrials.gov on 06/10/2022.

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

https://clinicaltrials.gov/ct2/show/NCT04585815

Trial Design:

ARM	INTERVENTION
Experimental: Sub-study B	Sasanlimab (SC) Axitinib (PO) SEA-TGT (IV)

Inclusion criteria:

- Histologically or cytologically confirmed locally advanced/metastatic (Stage IIIB-IV) NSCLC.
- At least one measurable lesion per RECIST v1.1 at Screening.
- ECOG Performance Status 0 or 1.
- Resolved acute effects of any prior therapy to baseline severity or CTCAE Grade ≤1.
- Adequate hepatic, renal, and bone marrow function.
- Previously untreated for locally advanced/metastatic NSCLC (Arms B1 & B2), or
- One or 2 prior lines of therapy for advanced/metastatic NSCLC (Arm B3), including immune checkpoint inhibitor treatment + chemotherapy, and have progressed during or after that therapy.
- PD-L1 TPS ≥1%

Exclusion criteria:

- Active or prior autoimmune disease that might deteriorate when receiving an immunostimulatory agent.
- Active non-infectious pneumonitis, pulmonary fibrosis, or known history of immune-mediated pneumonitis.
- Active infection requiring systemic therapy.
- Clinically significant cardiovascular disease.
- Other malignancy within 2 years of first dose, with exceptions.

- Symptomatic brain metastasis, with exceptions.
- Prior therapy with anti-PD-1, anti-PD-L1, or anti-PD-L2 agents.(Arms B1 & B2)
- Confirmed progressive disease on 1st or 2nd imaging tumor assessment after initiation of therapy for advanced/metastatic NSCLC.