AdvanTIG-205: Phase 2 trial of ociperlimab (OCI) + tislelizumab (TIS) + chemotherapy (chemo) in first line (1L) treatment of patients (pts) with locally advanced (LA), unresectable, or metastatic non-small cell lung cancer (mNSCLC)

Authors: Bo Zhu*,†,[1] Tae Min Kim*,[2] Shetal A. Patel,[3] Sagun Parakh,[4] Jia Tang,[5] Hongqian Wu,[6] Nicolas Girard[7]

Affiliations:

1. *Institute of Cancer, Xinqiao Hospital, Third Military Medical University, Chongqing, China*
2. *Department of Internal Medicine, Seoul National University Hospital, Cancer Research Institute, Seoul National University College of Medicine, Seoul, Korea*
3. *Department of Medicine, Division of Oncology, University of North Carolina School of Medicine, Chapel Hill, NC, USA*
4. *Department of Medical Oncology, Austin Hospital, Olivia Newton-John Cancer Research Institute, Melbourne, Victoria, Australia*
5. *Clinical Development, BeiGene (Shanghai) Co., Ltd., Shanghai, China*
6. *Global Statistics and Data Science, BeiGene USA, Inc., Ridgefield Park, NJ, USA*
7. *Institut du Thorax Curie Montsouris, Institut Curie, Paris, France*

Background: T-cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domains (TIGIT) is a co-inhibitory immune checkpoint receptor upregulated on T cells and natural killer cells in multiple solid tumors. Early phase clinical trials have shown antitumor activity of anti-TIGIT monoclonal antibodies (mAbs) + anti-programmed cell death protein 1 (PD-1) mAbs in pts with mNSCLC. OCI is a humanized mAb designed to bind to Fc-intact TIGIT with high affinity and specificity. In China, TIS, an anti-PD-1 mAb, is approved for 2/3L treatment of LA/mNSCLC, and 1L treatment of NSCLC with chemo. AdvanTIG-205 is a Phase 2 study (NCT05014815) designed to assess the efficacy and safety of OCI + TIS + chemo in 1L treatment of pts with LA, unresectable or mNSCLC.

Trial Design: Approximately 270 pts with histologically/cytologically confirmed squamous (sq) or non-squamous (non-sq) NSCLC, with no prior systemic therapy for advanced disease, and in whom driver mutation-directed therapy is not indicated, will be enrolled. Eligible pts will be randomized 1:1 to receive intravenous (IV) OCI 900 mg or placebo, with TIS 200 mg IV + chemo every 3 weeks (Q3W) for 4–6 cycles during the induction phase. For pts with sq NSCLC, chemo includes carboplatin (area under the concentration-time curve [AUC] 5 or 6, day [D] 1) + paclitaxel (P; 175 mg/m^2 or 200 mg/m^2, D1) or *nab*-P (100 mg/m^2, D1, D8 and D15) Q3W. For pts with non-sq NSCLC, chemo includes cisplatin (75 mg/m^2, D1) or carboplatin (AUC 5, D1) + pemetrexed (500 mg/m^2, D1) Q3W. For maintenance, pts will receive OCI or placebo, with TIS (+ pemetrexed for pts with non-sq NSCLC). Treatment will continue until intolerable toxicity, withdrawal of informed consent, or absence of benefit. Primary endpoint is progression-free survival in the intent-to-treat analysis set (per investigator [INV]; RECIST v1.1). Secondary endpoints include overall response rate, duration of response (both per INV; RECIST v1.1), overall survival, and safety. Exploratory endpoints include disease control rate, biomarker status and health related quality of life. This study is recruiting.