TPS9609 **Poster Session**

NEOSENT: Neoadjuvant anti-PD-1 therapy for patients with high-risk clinical stage II melanoma with a scheduled sentinel lymph node biopsy.

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Background: High-risk clinical stage II melanoma patients are already indicated for adjuvant anti-PD-1 therapy, regardless of the sentinel lymph node biopsy (SLNB) result, due to the high risk of relapse associated with pathological stages IIB/IIC or IIIC. Additionally, sentinel lymph node biopsy (SLNB) has no therapeutic effect, although studies have highlighted its prognostic value. Recent data also emphasize that delays in initiating adjuvant anti-PD-1 therapy are linked to poorer relapse-free survival rates. This study aims to investigate whether the early initiation of adjuvant anti-PD-1 therapy, or neoadjuvant anti-PD-1 therapy (for cases where sentinel node biopsy is subsequently classified as positive), is associated with improved outcomes. **Methods:** NEOSENT is a prospective cohort study with a historical control (quasi-experimental study). The inclusion criteria for the prospective cohort are as follows: high-risk clinical stage II melanoma (IIB/IIC) after excisional biopsy with negative margins, age over 18 years, absence of significant concomitant diseases, indication for sentinel lymph node biopsy (SLNB), and access to anti-PD1 treatment. Patients will undergo wide excision margins (WEM) and SLNB, scheduled for week 5 after initiating anti-PD1 therapy. A total of 1 year of anti-PD1 treatment is planned, consisting of either pembrolizumab (200 mg IV every 3 weeks for 18 cycles) or nivolumab (480 mg IV every 4 weeks). The protocol was reviewed and approved by the Institutional Review Board (IRB) prior to implementation. The historical cohort (control arm) includes patients with clinical stage IIB/IIC melanoma who were treated at the AC Camargo Cancer Center with WEM and SLNB, followed by at least one cycle of adjuvant anti-PD1 therapy. The primary objective of the study is to reduce the median time to initiation of anti-PD1 therapy by more than 30 days in the NEOSENT arm compared to the historical cohort. Secondary objectives include comparing relapse-free survival rates between the NEOSENT arm and the historical cohort using propensity score matching, as well as describing the pathological findings of SLNB after neoadjuvant anti-PD1 therapy and their correlation with survival outcomes. Research Sponsor: None.