TPS11586 **Poster Session**

The phase II study of pembrolizumab plus lenvatinib for patients with unresectable cutaneous angiosarcoma (Pembro-Lenva for cAS/PLAS trial).

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Background: Cutaneous angiosarcoma (cAS) is a rare cancer that often occurs in elderly people with common recurrence and metastasis after surgery. Chemotherapy, radiation therapy, and their combination are widely used, but their effectiveness is insufficient. With the increasing number of cAS patients due to the aging population, the development of effective treatment is urgently required. Previously, it has been reported that cancer shrank in 18% (5 out of 27) of patients after 2 months of paclitaxel administration in a clinical trial. Therefore, paclitaxel has become more commonly used for cAS. Other options include anthracycline anticancer drugs and gemcitabine. However, even with these anticancer drugs (and radiation therapy), cAS progresses quickly, and some reports have said that the 5-year survival rate is 9%. This study is planned to develop safer and more effective treatment for cAS. Pembrolizumab is an immune checkpoint inhibitor with PD-1 receptor-ligand interaction and lenvatinib is a multikinase inhibitor that inhibits tumor angiogenesis. The combination is expected to have strong therapeutic efficacy due to the immunomodulatory effects of pembrolizumab and the inhibitory effects of lenvatinib. **Methods:** This investigator-initiated, prospective, multicenter, non-randomized phase II trial evaluates the efficacy and safety of pembrolizumab plus lenvatinib for patients with unresectable cAS. Eligible patients are aged ≥18 years (≤85 years), histologically diagnosed with cAS, and both untreated and previously treated patients. The primary endpoint of this study is to confirm the response rate of pembrolizumab plus lenvatinib combination therapy for unresectable cAS based on RECST 1.1 at central review. The secondary endpoints are response rate (primary investigator assessment), progression-free survival, overall survival, disease control rate, duration of response, time to response, incidence of adverse events (AEs), incidence of drug-related adverse events (adverse drug reactions, ADRs), and incidence of serious AEs/ADRs. We estimated a threshold response rate of 18% and an expected response rate of 35%. The planned sample size is 38 patients (25 untreated patients and 13 treated) to provide a power of 70% with one-sided alpha of 5%. The planned accrual period is 2 years, and the follow-up period is 2 years; interim analysis will be performed at the enrollment of 20 patients is completed. The trial began in February 2025. Clinical trial information: NCT06673628. Research Sponsor: None.