TPS6114 Poster Session

A phase II study of AK117 combined with cetuximab or AK104 in the treatment of recurrent or metastatic head and neck squamous cell carcinoma after the failure of PD-1 (L1) inhibitors and/or platinum-based therapy.

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Background: The administration of first-line pembrolizumab monotherapy or pembrolizumab combined chemotherapy has been shown to improve survival among patients with recurrent or metastatic head and neck squamous cell carcinoma (R/M HNSCC). However, over 80% of the patients still experience disease progression within a year. Upon progression, treatment options are notably limited. Therefore, there is a dearth of a standardized treatment for R/M HNSCC after the failure of PD-1 (L1) inhibitors and/or platinum-based therapy. This study aims to assess the safety and efficacy of AK117 (anti-CD47) combined with Cetuximab or AK104 (PD-1/CTLA-4 Bispecial Antibody) in this patient subset. **Methods:** This is a non-randomized, two-group, phase II study. The inclusion criteria include: 1) Pathological or radiological diagnosis of R/M HNSCC (including oral cavity, oropharynx, larynx, and pharynx) and cannot be cured by local treatment; 2) Failure of PD-1 (L1) inhibitors and/or platinum-based therapy; 3) Eastern Cooperative Oncology Group (ECOG) Performance Status (PS) 0-1 and expected survival $\geq$3 months. Key exclusion criteria are active autoimmune diseases, use of immunosuppressive drugs, or any severe or uncontrolled systemic disease. We group the patients based on the duration of first-line PD-1 (L1) inhibitors from start to failure (Group 1: the duration $\leq$ 3 months; Group 2: the duration $>$ 3 months). Group 1 patients receive AK117 (45mg/kg, day 1, every 3 weeks) in combination with Cetuximab (initial dose 400mg/m^2, subsequent doses of 250mg/m^2, day 1, every week) maintained for one year or until progression or intolerable toxicity occurred. Group 2 patients are treated with AK117 (45mg/kg, day 1, every 3 weeks) in combination with AK104 (10mg/kg, day 1, every 3 weeks) maintained for one year or until progression or intolerable toxicity occurred. The primary endpoints are incidence of adverse events and overall survival. Secondary endpoints are objective response rate, progression free survival, disease control rate, and duration of response. Clinical trial information: NCT06508606. Research Sponsor: Akeso, Inc.