

TACTI-003: A Phase II study of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab in patients unselected for PD-L1 expression in first line metastatic head and neck squamous cell carcinoma (HNSCC).

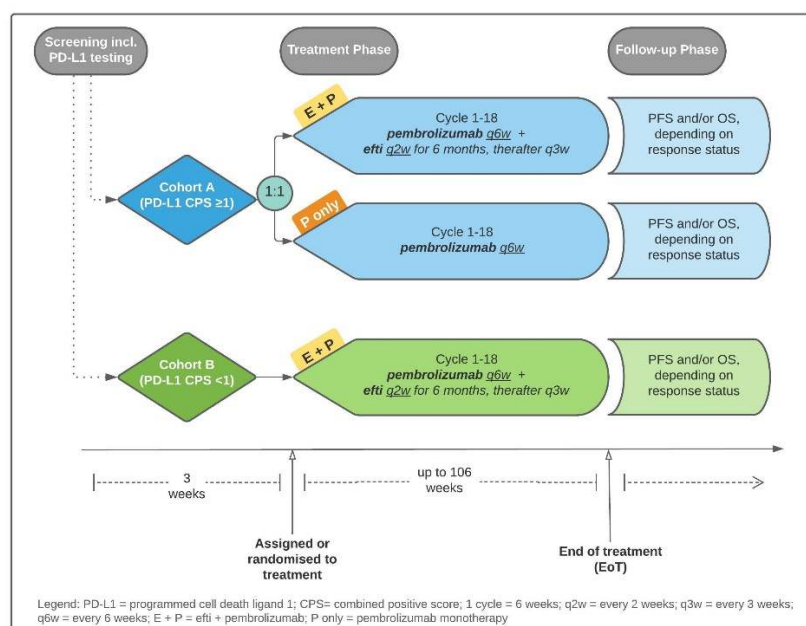
Background:

Eftilagimod alpha (efti) is a soluble LAG-3 protein targeting a subset of MHC class II molecules, effectively mediating antigen presenting cell (APC) and CD8 T-cell activation. Interim data from a phase II trial of efti plus pembrolizumab (TACTI-002) showed encouraging antitumor activity and manageable safety in patients treated for second line metastatic head and neck squamous cell carcinoma (HNSCC). TACTI-003 (NCT04811027) is the multicenter, open label, randomized phase II trial to investigate efti plus pembrolizumab in the first line setting for HNSCC patients.

Methods:

A planned total of 154 patients (pts), unselected for PD-L1 expression, will be recruited into two cohorts (Figure 1). In cohort A, CPS \geq 1 pts will be randomly assigned 1:1 to receive either efti (30 mg subcutaneously Q2W for initial 6 months, thereafter Q3W for up to 2 years) plus pembrolizumab (400 mg intravenously Q6W for up to two years) or pembrolizumab alone. CPS will be stratified (1-19 vs. \geq 20 and ECOG 0 vs. 1). Cohort B will include pts with CPS<1 who will receive efti plus pembrolizumab without randomization. Imaging will be performed every 9 weeks. The primary end point (EP) is objective response rate (ORR) by RECIST1.1. Secondary EPs include overall survival, ORR according to iRECIST, time to and duration of response, disease control rate, progression free survival, occurrence of anti-efti -specific antibodies, safety, and quality of life. Exploratory endpoints comprise biomarkers. The study has been approved by relevant competent authorities, ethic committees and IRBs.

Figure 1. Trial design



Type: Oral or Poster

Subcategory: Head and Neck Cancer

Second Category: Combination Immunotherapies

Keywords: Dendritic cells; Checkpoint blockade; Clinical Study; Clinical Trial;

Authors: Peguero J¹; Triebel F²

Affiliates:

¹⁻ Peguero: Oncology Consultants, P.A., Houston, USA

²⁻ Triebel: Research & Development, Immutep S.A.S., Orsay, France