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Initial results from a phase II study (TACTI-002) of eftilagimod alpha (soluble LAG-3 protein) and pembrolizumab as 2nd line treatment for PD-L1 unselected metastatic head and neck cancer patients

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Background

Eftilagimod alpha (efti) is a soluble LAG-3 protein that binds to a subset of MHC class II molecules to mediate antigen presenting cell (APC) activation and CD8 T-cell activation. The stimulation of the dendritic cell network and subsequent T cell recruitment with efti may lead to stronger anti-tumor responses in combination than observed with pembrolizumab alone. We hereby report initial results of the 2nd line head and neck squamous cell carcinoma (HNSCC) part of the phase II trial (NCT03625323).

Methods

The study has a Simon's 2-stage design, with objective response rate (ORR) as primary endpoint. Secondary endpoints included tolerability, disease control rate, progression free and overall survival, PK, PD and immunogenicity. Second line, PD-X naïve PD-L1 unselected HNSCC patients (pts) are eligible for the trial. Initially 18 pts were recruited in stage 1, an additional 18 pts (total N=36) recruited into stage 2 if the pre-specified threshold of >2 responses was reached. Efti was administered as 30 mg subcutaneous injection every 2 wks for 8 cycles and then every 3 wks for 9 cycles with pembrolizumab (200 mg intravenous infusion every 3 wks for up to 2 yrs).

Results

Between Mar 2019 and Dec 2019, 18 pts were enrolled into stage 1. The median age was 66 yr (range 48-84) and 94 % were male. The ECOG PS 0:1 was 56 % and 44 % respectively. Pts from all PD-L1 subgroups (CPS < 1 %, 1-20%, ≥20 %) were recruited. Pts received a median of 5 pembrolizumab and 7 efti administrations. All pts in stage 1 (n=18) were evaluable. Six pts (33 %) had a partial response (iPR), 1 patient (6 %) had a complete response and 2 (11 %) had stable disease according to iRECIST representing an ORR (DCR) of 39 % (50 %). Threshold for opening stage 2 (> 2 responses) was met. The most common (> 10 %) adverse events (AEs) were cough (29 %), asthenia (24 %), decreased appetite (18 %), dyspnea (18 %), fatigue (17 %), diarrhea (15 %) and nausea (12 %). Seven (7; 41 %) pts are still on therapy and median PFS is not yet reached.

Conclusions

Efti in combination with pembrolizumab is safe and shows encouraging antitumor activity in 2nd line HNSCC patients.

Clinical trial identification

EudraCT Number: 2018-001994-25; NCT03625323.

Legal entity responsible for the study

Immutep S.A.S.

Funding

Immutep S.A.S.

Disclosure

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