A008: Real-world comparator study: MVX-ONCO-1, a cell-based immunotherapy currently in Phase II, shows prolonged OS and PFS for patients with recurrent/metastatic Head & Neck squamous cell carcinoma (R/M HNSCC)

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BACKGROUND: MVX-ONCO-1 is an active-personalized cancer vaccine composed of irradiated autologous tumour cells and genetically modified encapsulated cells delivering standardized, sustained, stable level of the potent adjuvant granulocyte-macrophage colony stimulating factor (GM-CSF) at the vaccine site. Currently a multicentre Phase IIa trial evaluating its safety, feasibility and efficacy in R/M HNSCC patients (pts) in ≥ second line systemic therapy is ongoing (SAKK 11/16). This real-world study was designed to contextualize the phase 2 single-arm trial results by creating an external comparator arm.

METHODS: All 16 R/M HNSCC pts treated with MVX-ONCO-1 by April 1st 2022 are included in this analysis (14 from the ongoing SAKK11/16 trial and 2 from the Phase I trial). Eligible pts had R/M HNSCC progressing after at least one line of systemic therapy, including anti-PD-1 checkpoint inhibitor (CPI) in 13 pts. The vaccine therapy consists of 6 administrations weekly for 4 weeks followed by 2 boosters 2 weeks apart without maintenance. One administration consists of sub-cutaneous (sc) implantation of 2 capsules containing GM-CSF secreting cells and a sc injection of irradiated autologous tumour cell suspension.

A real-world comparator cohort was built with pts from two clinical sites from IQVIA's Oncology Evidence Network: University Hospital Frankfurt, Germany and Portuguese Oncology Institute of Porto, Portugal. Real-world adapted inclusion/exclusion (I/E) criteria from the SAKK 11/16 trial were applied resulting in a cohort of 62 pts which were treated according to the respective local guidelines (chemotherapy, cetuximab, CPI).

To improve comparability, the two cohorts were balanced at line of therapy (LOT) level along pre-defined prognostic factors (age, gender, year of advanced HNSCC diagnosis, time from initial to advanced stage diagnosis, tumour site, WHO score, Human Papilloma Virus (HPV) status, previous radio-chemotherapy or immunotherapy, and LOT number). Balance between the weighted cohorts was assessed. Balancing on LOT level rather than on pt level increases the sample size in the real-world comparator, as one eligible pt can have multiple eligible LOTs.

The primary objective was to evaluate the efficacy of MVX-ONCO-1 versus anti-cancer therapies in real-world practice using overall survival (OS), survival rate at 26 weeks, time to next therapy (TTNT) and progression-free survival (PFS). Results were verified with several sensitivity and subgroup analyses.

RESULTS: The 16 trial and 62 comparator pts were balanced for key prognostic variables (listed above). Median OS in the trial population was not reached (95% confidence interval

(CI): 6.8 months, NA) vs 7.6 months (6.0, 9.2) in the comparator cohort. OS at 26 weeks was 87.1% (73.8, 100.0) versus 60.2% (49.5, 73.1) respectively, and therefore there was an absolute risk reduction (ARR) of death at 26 weeks due to MVX-ONCO-1 of 26.9% (8.4, 35.4). Median TTNT was 4.1 months (1.8, NA) in the trial cohort versus 8.7 months (7.3, 14.9) and median PFS was 4.1 months (1.8, NA) in the trial cohort and 2.7 months (2.1, 3.5) in the comparator cohort. Prolonged survival was observed in both HPV pos and HPV neg R/M HNSCC pts. No systemic adverse reaction related to the personalized immunotherapy was reported.

CONCLUSIONS:

The data from this Real-World Comparator Study shows that in heavily pre-treated R/M HNSCC pts, cell-based immunotherapy with MVX-ONCO-1 improved both OS and PFS. Indeed, we observed a clinically meaningful ARR of death at 26 weeks of 26.9%. Detailed analysis will be presented at the meeting. MVX-ONCO-1 treatment is feasible, safe and well tolerated. Pts in both cohorts had received post-study treatment, which may indicate a potential benefit to combine the MVX-ONCO-1 vaccine with other therapies to achieve further clinically relevant survival benefits.

Abstract Body