Phase II study of monalizumab, a first-in-class NKG2A monoclonal antibody, in combination with cetuximab in previously treated recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN)


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Background

Objective response rate (ORR) of monalizumab in combination with cetuximab in previously treated patients with recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN) was the primary objective of the study. The activity of monalizumab combined with cetuximab (ORR of 27.5%, median progression-free survival of 5.0 months and median overall survival of 10.3 months) appears superior to previous studies with cetuximab (ORR of 16.1%, median progression-free survival of 3.7 months and median overall survival of 7.1 months).

Key eligibility criteria

- R/M SCCHN histologically confirmed, HPV (+) or HPV (-).
- Previous treatment N=40
- Radiation
- Surgery
- Stable disease (SD) 16 (40%)
- Partial response (PR) 10 (25%)
- Complete response (CR) 1 (2.5%)
- Progressive disease (PD) 20 (50%)
- Median Time to Response [min-max] 1.6 months [1.5-3.9]
- Median Duration of Response 5.6 months [3.8-7.9]
- Median Duration of Response 5.0 months [3.7-6.9]
- Median overall survival 10.3 months [7.1-13.9]
- Received both prior platinum-based chemotherapy and PD-(L)1 inhibitors.

Conclusions

- These data confirm the anti-tumor activity of monalizumab in combination with cetuximab in patients with R/M SCCHN showing deep and durable responses.
- The activity of monalizumab combined with cetuximab (ORR of 27.5%, median PFS of 5 months and median OS of 10 months) appears superior to cetuximab alone based on historical data (ORR 12.6%, PFS 2.3 months, OS 5.6 months) (1,10).
- The combination monalizumab and cetuximab is well tolerated without potentiation of cetuximab side effects (7).
- This study continues to enroll additional patients with R/M SCCHN who received both prior platinum-based chemotherapy and PD-L1 inhibitors.

References