The AIM-HN Study: A registrational-directed study evaluating the efficacy of tipifarnib in patients with recurrent or metastatic head and neck squamous cell carcinoma with HRAS mutations

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HRAS mutations define a unique molecular subset of ~4-8% of head and neck squamous cell carcinoma (HNSCC)1. Evidence suggests that these tumors respond poorly to standard systemic therapy, and the impact of HRAS missense mutations on clinical outcomes is currently being evaluated.

Tipifarnib is a potent, selective inhibitor of farnesyltransferase, a critical enzyme required for HRAS activity2.

Data from a Phase 2 proof of concept study for tipifarnib in HRAS mutant HNSCC demonstrated an overall response rate of 55% (95% CI, 31.5 to 76.9), a median progress-free survival of 5.6 months, and a median overall survival of 15.4 months in patients with high variant allele (VAF) frequency (≥20%). These patients had received a median of two prior lines of systemic therapy. The safety profile of tipifarnib was tolerable and manageable in this study3.

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