Phase 1b Study of MEHD7945A (DULIGOTUZUMAB) Plus Cisplatin/Flourouracil or Carboplatin/Paclitaxel for First-Line Treatment of Recurrent/Metastatic Squamous Cell Carcinoma of Head and Neck


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OBJECTIVES

- Primary Objectives
  - Evaluate the safety and tolerability of MEHD7945A administered IV q4w in combination with chemotherapy regimens (Figure 2)
  - Additional Objectives
    - Characterize the pharmacokinetics of MEHD7945A and chemo components
    - Preliminary assessment of the anti-tumor activity

METHODS

Study Design

- Phase 1b, open-label multicenter study, enrolling patients with R/M SCCCHN not amenable to curative local therapy; no prior therapy for R/M disease
- Modified 3 + 3 + 3 design
- In xenograft models, MEHD7945A showed equal or superior activity over monospecific antibodies, including EGFR resistant models, and enhances activity of various cytotoxic chemotherapies

RESULTS

- Data cut-off date: 24 Jul 2014
- Disposition
  - Enrolled 24 patients (9 Arm A, 15 Arm B), 16 patients active on treatment
- Treatment by Investigators Occurring in More Than 10% of Patients.
- Objective Response Rate
  - Included in tumor response analysis
- Disease Progression
  - Partial Response
  - Complete Response
  - Median (months)

Table 3. Grade 3-4 Events – All and Assessed as Related to Any Study Treatment by Investigators Occurring in More Than 10% of Patients.

CONCLUSIONS

- Phase 1b data on the combination of MEHD7945A at 1650 mg q4w with cisplatin/5FU (Arm A) or carboplatin/paclitaxel (Arm B) chemotherapy in 1L R/M SCCCHN suggests
- Frequent and severity of select adverse events compared to historical data with combination of chemotherapy and EGFR inhibitors
- No new safety signals overall through likely potentiation of chemotherapeutic related AEs leading to frequent chemo dose reductions
- Increased frequency and severity of select adverse events compared to historical data with combination of chemotherapy and EGFR inhibitors

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