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SSM24-05

NBTXR3 Hafnium Oxide Nanoparticles Activated by IMRT for the Treatment of Locally-Advanced HNSCC in Frail and/or Elderly Patients: A Phase I/II Study

Wednesday, Dec. 4 3:40PM - 3:50PM Room: S104A

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PURPOSE

Elderly head and neck squamous cell carcinoma (HSNCC) patients (pts) ineligible for standard of care treatment require new therapeutic approaches. NBTXR3, hafnium oxide nanoparticles, may represent such an option. NBTXR3 is activated by radiotherapy, enhancing its effects, leading to physical destruction of cancer cells. A Phase I/II trial [NCT01946867] is underway to evaluate NBTXR3 in elderly (>=70 years) or frail pts with HNSCC of the oral cavity and oropharynx ineligible for cisplatin or intolerant to cetuximab.

METHOD AND MATERIALS

Pts received a single intratumoral injection of NBTXR3 and intensity modulated radiation therapy (IMRT; 70 Gy/35 fractions/7 weeks). The study was a 3 + 3 dose escalation to test the NBTXR3 dose equivalent to 5, 10, 15, and 22% of baseline tumor volume, followed by a dose expansion. Primary endpoints include Recommended Phase 2 Dose (RP2D) determination and early dose limiting toxicities (DLT). Presence of NBTXR3 in surrounding healthy tissues and efficacy (RECIST 1.1 principles) were also evaluated.

RESULTS

Enrollment for the dose escalation phase was completed at all dose levels: 5% (3 pts), 10% (3 pts), 15% (5 pts), and 22% (8 pts). No early DLT or SAE related to NBTXR3 or injection were observed. One G1 AE (asthenia; 22%) related to NBTXR3 and four AEs (G2 oral pain, G1 tumor hemorrhage, G1 asthenia, and G1 injection site hemorrhage) related to injection were reported. RT-related toxicity was as expected. The RP2D has been determined to be 22%. CT-scan assessment demonstrated absence of NBTXR3 in surrounding tissues. Among 13 evaluable pts treated at doses >=10%, 9 achieved complete response of the injected lesion. The final dose escalation safety results will be presented herein.

CONCLUSION

NBTXR3 was well tolerated at all tested doses and demonstrated a good safety profile. A dose expansion phase has started with the identified RP2D. NBTXR3 is currently being evaluated in a phase II/III trial in soft tissue sarcoma [NCT02379845] and phase I/II trials in prostate [NCT02805894], liver [NCT02721056] and rectal [NCT02465593] cancers.

CLINICAL RELEVANCE/APPLICATION

The results of this study highlight the potential of NBTXR3 as a novel treatment option for elderly and/or frail pts with locally advanced HNSCC and address an unmet medical need.

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