P2.260: Re-irradiation (ReRT) with NBTXR3 for Inoperable Locoregionally Recurrent Non-Small Cell Lung Cancer (NSCLC): A Phase I Trial

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INTRODUCTION

- Re-irradiation (reRT) of inoperable, locoregionally recurrent NSCLC after prior RT is often limited to palliative doses due to normal-tissue tolerance.
- NBTXR3, a novel hafnium-oxide nanoparticle injected directly into tumors, amplifies intra-tumoral energy deposition during RT, enhancing the therapeutic ratio.
- The safety of NBTXR3 with reRT was previously reported in a phase I dose escalation study.
- Aim: Assess safety and early efficacy from pooled dose escalation and expansion phase.

METHODS

Eligibility:
- Stage IA-IV biopsy proven recurrent NSCLC within prior RT field

Exclusion:
- History of RT within prior 6 months, G4 RT toxicity, or interstitial lung disease

NBTXR3 Intra-Tumoral Injection Dose:
- Pts received RT after NBTXR3 intra-tumoral injection dose of 22% or 33% of gross tumor volume (GTV) on RT planning CT scan in escalation phase and 33% of GTV in the expansion phase
- Up to 4 sites were allowed to be injected

RT dose:
- 45 Gy in 15 fractions
- 30 Gy in 10 fractions permitted

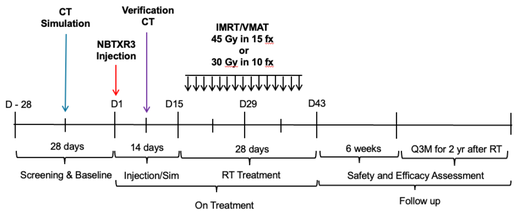
Definition of Dose limiting toxicities (DLTs):
- Any CTCAE v5.0 G3+ adverse events (AEs) related to NBTXR3 or RT within 2 months of NBTXR3 injection

Local progression free survival (LPFS) and overall survival (OS):
- Estimated by the Kaplan-Meier method

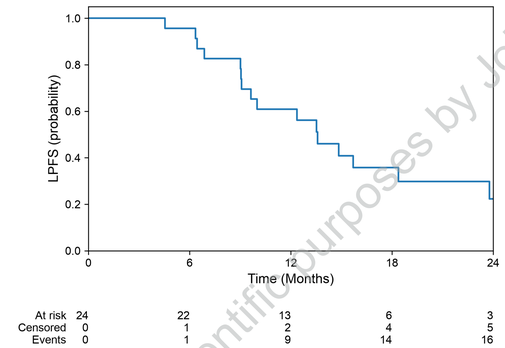
DISCUSSION and CONCLUSIONS

- **Intratumoral NBTXR3 plus reRT is feasible and safe for locoregionally recurrent NSCLC**
- **NBTXR3 may permit clinically meaningful local control using a substantially lower reRT dose**

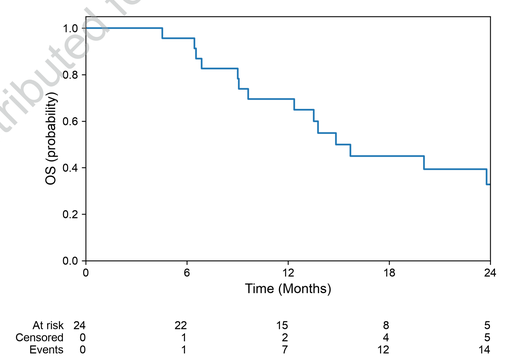
STUDY SCHEMA



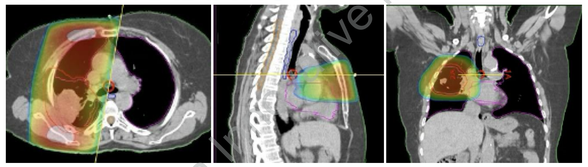
LOCAL PROGRESSION FREE SURVIVAL



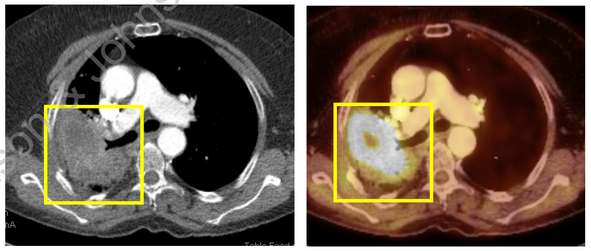
OVERALL SURVIVAL



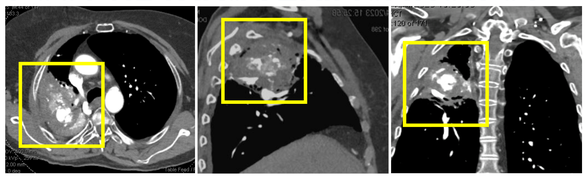
INITIAL RADIATION PLAN



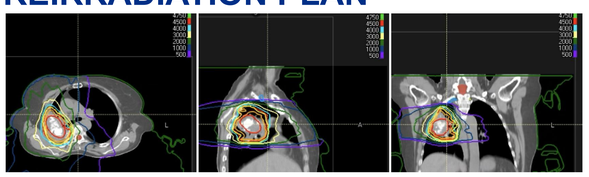
RECURRENCE



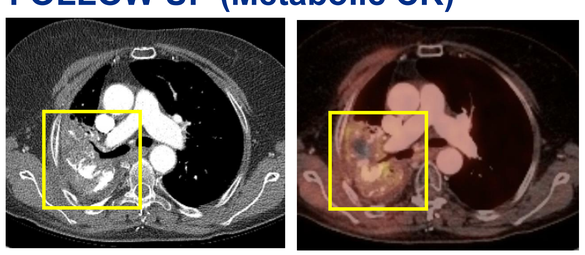
POST NBTXR3 VERIFICATION CT



REIRRADIATION PLAN



FOLLOW UP (Metabolic CR)



RESULTS

Demographics:
- From 2022 to 2025, 24 pts enrolled
- SCC: 17pts (71%), Adenocarcinoma: 7 pts (29%)
- Median age: 70 years, (range 47-91)
- Median prior RT dose: 60 Gy (range 30-74)

Treatment Details:
- 31 sites injected and treated (2 sites in 4 pts, 4 sites in 1 pt): 8 mediastinal lymph nodes and 23 lung lesions (22 central, 1 peripheral)
- NBTXR3 injected bronchoscopically (19 pts) or percutaneously (5 pts)
- Median Tumor volume: 26 mL (range 3-324)
- Median NBTXR3 volume: 8 mL (range 1-90)
- NBTXR3 dose: 22% (3 pts), 33% (21 pts)
- reRT Dose: 30-37.5 Gy (3 pts), 45-52.5 Gy (21 pts)

Safety:
- All 24 pts completed treatment without DLTs
- Median follow-up: 12 months (range 2-39)
- G3 RT-related AEs: 33% (n=8)
  - Dyspnea (n=3), infection (n=3), lymphopenia (n=1), hypotension (n=1), tachycardia (n=1), dysphagia (n=1), aspiration (n=1), pain (n=1), fistula (n=1), thromboembolus (n=1)
- G5 RT-related AEs: 8% (n=2)
  - Respiratory failure 6 months after reRT (n=1), pulmonary hemorrhage 5 months after reRT (n=1)
- No G3-5 NBTXR3 or injection related AEs

Efficacy:
- Locoregional control rate: 1-year 79% (11/14 pts)
- LPFS: 1-year 61%, median 13.6 months
- OS: 1-year 70%, median 14.8 months

CLINICAL TRIAL ID

NCT04505267

FUNDING

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