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Abstract CT013: Phase I trial evaluating BNT116, a TAA-encoding mRNA vaccine, in combination with cemiplimab in frail patients with advanced non-small cell lung cancer (NSCLC) FREE

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Abstract

Background:

First-line platinum-based chemotherapy (PBC) for NSCLC extends survival; however, many patients (pts) with considerable comorbidities or older age are unable to tolerate PBC. BNT116, an intravenously administered, unmodified RNA-based lipoplex cancer vaccine, is composed of six mRNAs (CLDN6, KK-LC-1, MAGE-A3, MAGE-A4, MAGE-C1, PRAME), each encoding a tumor-associated antigen (TAA) frequently expressed in NSCLC. In early studies, it demonstrated a favorable safety profile alone or in combination with cemiplimab. We present preliminary data for BNT116 plus cemiplimab in frail patients with advanced or metastatic NSCLC who were not eligible for PBC as first-line treatment.

Methods:

The open label, multiple cohort Phase I LuCa-MERIT-1 (NCT: 05142189) clinical trial aims to determine the safety (dose limiting toxicities; treatment-emergent adverse events) and clinical activity (RECIST v1.1) of BNT116, alone or in combinations. The findings from this cohort will evaluate BNT116 in combination with cemiplimab in frail pts (ECOG PS 0-2) who are not candidates for first-line chemotherapy as per investigator's assessment and had a PD-L1 tumor proportion score (TPS) ≥1% on tumor cells. Biomarker analysis includes immunogenicity (ELISpot, n=7), cytokines (MSD, n=19), ctDNA (Avenio ctDNA Surveillance, n=19), and PD-L1 (IHC, n=20).

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Results:

As of 01 DEC 2024, 20 pts (median age 69.5 years; 30% ECOG 0, 60% ECOG 1, 10% ECOG 2) received BNT116 in combination with cemiplimab. Treatment-related adverse events (TRAEs) to BNT116 were experienced by all pts, while 13 pts (65%) experienced cemiplimab TRAEs. BNT116 TRAEs ≥G3 were observed in 3 pts (15%) and included supraventricular tachycardia (n=1 [5%]), hypoxia (n=1 [5%]), and hypertension (n=1 [5%]). Cemiplimab TRAEs ≥G3 were observed in 2 pts (10%). Serious TRAEs were observed in 7 pts (35%), in 3 pts (15%) only related to BNT116 and in 3 pts (15%) only related to cemiplimab, with no fatal TRAEs. The best overall response was a partial response (PR) in 9 of 20 pts (45%), and stable disease in 7 of 20 pts (35%). Of the 9 PR pts, 2 had a PD-L1 TPS <50%. The confirmed objective response rate was 45%, the disease control rate was 80%, and median progression-free survival was 9.9 months (95% CI: 2.4, not estimable). Frail pts were able to mount a robust type 1 interferon cytokine response and *de novo* T-cell responses to multiple TAAs detected via *ex vivo* IFNγ ELISpot, which were comparable to non-frail pts in other cohorts. ctDNA analysis revealed strong molecular responses following treatment evidenced as early as week 3.

Conclusions:

BNT116 plus cemiplimab demonstrated promising anti-tumor activity, consistent immune response induction, and a manageable safety profile in frail pts with advanced NSCLC. Updated safety and clinical activity data will be presented along with biomarker data.

Citation Format:

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