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Overall survival (OS) analysis of telisotuzumab adizutecan in patients (pts) with nonsquamous non-small cell lung cancer (NSQ NSCLC): Phase 1 first-in-human study

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Background

c-Met (or MET) protein is highly expressed in NSCLC and has a poor prognosis. Telisotuzumab adizutecan (ABBV-400; Temab-A) is an antibody drug conjugate (ADC) consisting of an anti c-Met antibody conjugated to a Top1i payload. In an ongoing phase 1 study (NCT05029882), Temab-A showed promising efficacy and manageable safety in pts with NSQ NSCLC. Herein, we present OS for pts with NSQ NSCLC.

Methods

Enrolled pts with advanced *EGFR* wildtype (WT) or mutant (MUT) NSQ NSCLC that progressed after platinum-based chemotherapy and immune checkpoint or targeted therapy received Temab-A once every 21 days. Primary endpoint was confirmed investigator-assessed objective response rate (ORR) per RECIST v1.1. Secondary endpoints included duration of response (DOR), progression-free survival (PFS) and OS. Tumor tissue c-Met protein expression was retrospectively assessed by IHC via central laboratory.

Results

The *EGFR* WT cohort enrolled 48 pts (median follow-up: 27 months [mo]; median prior lines of therapy [LoT] 2 [range, 1–9]) and the *EGFR* MUT cohort enrolled 41 pts (median follow-up: 26 mo; median prior LoT: 3 [1–8]). Most pts received 2.4 mg/kg dose (*EGFR* WT: 81%, 39/48; *EGFR* MUT: 88%, 36/41); the remaining received 3.0 mg/kg. Median duration of treatment was 5.6 and 10 mo in the *EGFR* WT and *EGFR* MUT cohorts, respectively. Median OS for *EGFR* WT and *EGFR* MUT was 13.8 mo and 16.2 mo (Table). Among *EGFR* WT patients, the prevalence of c-MET expression $\geq 3+$ staining intensity in $\geq 10\%$ and $\geq 25\%$ tumor cells was 43% (20/46) and 33% (15/46), respectively. Among *EGFR* MUT patients, it was 56% (19/34) and 41% (14/34), respectively. Median OS was longer in *EGFR* WT pts with c-MET above these thresholds ($\geq 3+$, $\geq 10\%$: 25.2 mo; $\geq 3+$, $\geq 25\%$: 19.2 mo). No new safety signals were observed. Table: 2658RO

	<i>EGFR</i> WT		<i>EGFR</i> MUT			
	Total N=48 ^a		$\geq 3+$, $\geq 10\%$ n=20 ^b	$\geq 3+$, $\geq 25\%$ n=15 ^b	Total N=41 ^c	
ORR, n (%)	24 (50)		12 (60)	9 (60)	26 (63)	
Median DOR, mo (95% CI)	5.6 (4.2–12.3)		5.6 (3.8–12.4)	6.3 (2.8–21.8)	9.7 (8.3–12.4)	
Median PFS, mo (95% CI)	6.8 (5.4–7.3)		7.2 (5.5–9.0)	8.0 (5.3–9.8)	10.9 (8.3–12.3)	
Median OS, mo (95% CI)	13.8 (9.0–25.2)		25.2 (7.5–NE)	19.2 (7.1–NE)	16.2 (11.6–19.9)	
					15.6 (10.6–19.6)	16.2 (10.6–21.0)

^a3.0 mg/kg (n=9). ^bAvailable IHC. ^c3.0 mg/kg (n=5). DOR, duration of response; IHC, immunohistochemistry; mo, months; NE, not estimable; ORR, objective response rate.

Conclusions

Temab-A exhibited promising OS in a heavily pretreated NSCLC population. OS rates compared favorably to those reported in the same indications with chemotherapy or other ADCs.

Clinical trial identification

NCT05029882.

Editorial acknowledgement

Medical writing support was provided by Bio Connections LLC and funded by AbbVie.

Legal entity responsible for the study

AbbVie funded this study and participated in the study design, research, analysis, data collection, interpretation of data, reviewing, and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship.

Funding

AbbVie funded this study and participated in the study design, research, analysis, data collection, interpretation of data, reviewing, and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship.

Disclosure

D. Sommerhalder: Financial Interests, Personal, Other, Ad-hoc advisory role: Syneos SAG; Financial Interests, Personal, Other, Medical consulting: Guidepoint; Financial Interests, Personal, Advisory Board, One-time advisory role: Nimbus Therapeutics, Revolution Medicine; Financial Interests, Personal, Advisory Board, One time advisory role: Cartography Bio; Financial Interests, Institutional, Full or part-time Employment, Employed as a physician by Texas Oncology, a for-profit entity.: Texas Oncology/US Oncology; Financial Interests, Personal, Stocks/Shares, Shareholder. 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