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1381P TOGETHER: Pooled real-world datasets of METex14 skipping NSCLC and adjusted comparison of upfront (chemo-) immunotherapy with tepotinib from VISION

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Background: The TOGETHER study was designed for flexible pooling of METex14 skipping non-small cell lung cancer (NSCLC) patient (pt) datasets to characterize real-world (rw) outcomes before approval of MET inhibitors.

Methods: Seven datasets were used to analyze rw progression-free (rwPFS) and overall (rwOS) survival in advanced NSCLC with METex14 skipping according to Kaplan-Meier. Indirect treatment comparisons (ITC) were performed with propensity score reweighting of pts who received first-line (1L) immunotherapy (IO) alone or with chemotherapy (chemo) to match the characteristics of 111 pts with positive tissue biopsies (T+) who received 1L tepotinib in the VISION study (NCT02864992; data cut: Nov 2022).

Results: As of Jan 2023, TOGETHER included 309 pts (mean [SD] age 71.1 [9.7] years, 48% male, 52% with smoking history [SM]), with 615 lines of therapy administered between 2004 and 2022. For 1L IO+chemo (n=26; mean age 66.8 [SD 12.4], 65% SM) median rwPFS in TOGETHER was 5.7 months (95% CI: 3.1, 17.5) before and 6.9 mo (95% CI: 5.7, 29.4) after weighting, compared with 15.9 mo (95% CI: 11.3, ne) for 1L tepotinib (HR 0.52 [0.29, 0.93]; p=0.03). For 1L IO monotherapy (n=48; mean age 73.2 [SD 9.1], 67% SM), median rwPFS in TOGETHER was 3.9 mo (95% CI: 2.7, 7.1) before and 3.4 mo (95% CI: 2.0, 9.7) after weighting compared with 15.9 mo for 1L tepotinib (HR 0.37 [0.24, 0.58]; p<0.01). Although confounded by subsequent treatments, median OS was also longer for tepotinib with 29.7 mo (95% CI: 19.1, ne) compared with 22.1 mo (95% CI: 12.6, ne) for IO+chemo (HR 0.77; p=0.38) and 18.9 mo (HR 0.64; p=0.05) for IO monotherapy. Other rw 1L treatments were chemo (n=128; mean age 69.3 [SD 9.5], 55% SM) with a median rwPFS of 4.8 mo (95% CI: 4.1, 6.2), and crizotinib (n=62; mean age 74.6 [SD 11.0], 56% SM) with a median rwPFS of 7.4 mo (95% CI: 4.4, 10.9). Median rwPFS was shorter for 2L+ chemo (4.3 mo, n=95) or 2L+ IO monotherapy (3.3 mo, n=83), and longer for 2L+ crizotinib (8.1 mo, n=68).

Conclusions: This large retrospective analysis shows poor rw outcomes for METex14 skipping NSCLC pts under standard treatments prior to the uptake of novel MET inhibitors. Matched ITC suggests longer PFS and OS with 1L tepotinib compared with 1L IO+chemo or IO monotherapy.

Clinical trial identification: NCT02864992.

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1382P Liquid biopsies (LBx) and tissue biopsies (TBx) for identifying MET exon 14 (METex14) skipping in advanced NSCLC: Analyses from the phase II VISION study of tepotinib

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Background: LBx and TBx have complementary roles in detection of NSCLC driver alterations, such as METex14, which predicts efficacy of MET inhibitors. The only MET inhibitor trial to enroll based on prospective detection of METex14 in LBx and/or TBx is the VISION trial of tepotinib. We evaluated patient (pt) characteristics and outcomes according to METex14 positivity in LBx and/or TBx (data cut-off: Nov 20, 2022).

Methods: METex14 was centrally assessed in prescreening by NGS analysis of fresh LBx (Guardant360[®] or Archer[®]MET) and/or archival or fresh TBx (OncoPrint Focus or Archer[®]MET). Pts in Japan could enroll based on local TBx RT-PCR via the LC-SCRUM program. Parallel LBx/TBx testing was recommended but not mandatory. Eligibility required LBx-positive (L+) and/or TBx-positive (T+) status.

Results: Of 313 pts, 208 (66.5%) were T+ and 178 (56.9%) were L+. L+ pts had worse baseline prognostic features than T+ pts, including more pts with ≥ 3 target lesions (27.5% vs 18.8%) or ECOG PS 1 (76.4% vs 72.1%), higher median sum of target lesion diameters (67.1 vs 55.2 mm) and worse health-related quality of life (mean EORTC QLQ-C30 GHS, 53.9 vs 60.1). In 180 T+ pts with matching LBx results, METex14 was detected in ctDNA (L+) in 74 (41.1%) (i.e. T+/L+) and was undetectable (L-) in 106 (58.9%) (i.e. T+/L-). ORRs were slightly higher in T+/L+ pts, but T+/L- pts had longer DOR, PFS and OS. Overall meaningful durable efficacy was seen in treatment-naïve and previously treated pts (Table).

Table: 1382P

	Treatment-naïve		Previously treated	
	T+/L- (n=52)	T+/L+ (n=42)	T+/L- (n=54)	T+/L+ (n=32)
ORR, % (95% CI)	57.7 (43.2, 71.3)	64.3 (48.0, 78.4)	44.4 (30.9, 58.6)	53.1 (34.7, 70.9)
mDOR, months (95% CI)	ne (10.4, ne)	19.4 (7.6, ne)	12.6 (5.1, 20.8)	9.9 (4.4, 15.4)
mPFS, months (95% CI)	22.1 (14.8, ne)	12.1 (7.8, 49.7)	13.8 (8.2, 24.9)	8.2 (5.5, 13.7)
mOS, months (95% CI)	32.7 (15.3, ne)	28.5 (14.2, ne)	20.8 (15.6, 32.5)	19.8 (10.0, 26.5)

CI, confidence interval; DOR, duration of response; m, median; ORR, objective response rate; OS, overall survival; PFS, progression-free survival.

Conclusions: Tepotinib had robust and durable activity in T+ pts with L- or L+ status. While both LBx and TBx are suitable and complementary for detecting METex14, LBx may preferentially select pts with a poorer prognosis and higher tumor load. Undetectable METex14 in baseline ctDNA may define a more favorable treatment

outcome. Differences in populations identified by TBx and LBx should be considered when interpreting trial data.

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1383P Efficacy of capmatinib compared to standard of care for German patients with locally advanced or metastatic NSCLC harboring METex14 mutations: Results from the RECAP study

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Background: Capmatinib, a selective MET inhibitor, is approved by EMA and other health authorities worldwide for the treatment of adult patients (pts) with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring MET exon 14 skipping (METex14) mutations. The RECAP study provided comparative evidence of capmatinib vs standard of care (SoC) in first (1L) and second line (2L) NSCLC pts with METex14 mutations (NCT05796726).

Methods: The RECAP study is a historical comparison of capmatinib pts from the GEOMETRY mono-1 study with an external control arm of SoC pts from German routine care collected via a retrospective chart review. Analyses were performed both naïve and propensity score adjusted. Evaluated outcomes included efficacy endpoints such as overall survival (OS), progression-free survival (PFS), overall response rate (ORR), time to CNS progression (CNSprog) and exploratory safety endpoints.

Results: A total of 119 1L and 46 2L pts were included in the chart review and compared to 60 1L and 81 2L pts treated with capmatinib. For 1L pts, the naïve comparison showed a significant benefit of capmatinib for OS (median 25.49 vs 14.59 months; HR 0.58; 95% CI 0.39-0.87; p=0.011), PFS (median 12.45 vs 5.03 months; HR 0.44; 95% CI 0.31-0.63; p<0.001) and ORR (event rate 68.3 vs 26.9%; RR 2.54; 95% CI 1.80-3.58; p<0.001). In 2L, OS, PFS and ORR showed trends favoring capmatinib with no significant results. Notably, CNSprog resulted in a significant benefit with