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## 33P A literature review of Stevens-Johnson syndrome (SJS)/toxic epidermal necrolysis (TEN) caused by immune checkpoint inhibitors (ICIs), epidermal growth factor receptor tyrosine kinase inhibitors (EGFR-TKIs) and multikinase inhibitors (MKIs)

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**Background:** Stevens-Johnson syndrome (SJS)/ Toxic epidermal necrolysis (TEN) is the most severe type of drug eruption, characterized by blisters and generalized epidermolysis. Immune checkpoint inhibitors (ICIs), epidermal growth factor tyrosine kinase inhibitors (EGFR-TKIs), and multi-kinase inhibitors (MKIs) are three types of molucular therapy popularly used in advanced non-small cell lung cancer (NSCLC). The therapies can cause keratinocytes apoptosis, leading to SJS/TEN, which is not common but always life-threatening.

**Methods:** We performed a retrospective analysis of case reports about ICIs, EGFR-TKIs, MKIs induced SJS/TEN by exploring PubMed, the Embase database, CNKI and WanFang.

**Results:** We analyzed 32 cases of SJS/TEN caused by ICIs (pembrolizumab, 11; nivolumab, 10; Ipilimumab + nivolumab, 5; Tislelizumab, 2; Toripalimab, 1; atezolizumab, 1; Camrelizumab, 1; Sintilimab+Toripalimab, 1). SJS/TEN could occur from 1 week to 5 months after initiation of ICIs, which was usually 1-2 cycles of treatment. SJS/TEN caused by ICIs is characterized by severe condition and high mortality. 11/32 patients were dead (pembrolizumab, 3; nivolumab, 3; Ipilimumab + nivolumab, 4; Sintilimab+Toripalimab, 1). Almost all patients who developed serious SJS/TEN had presymptoms, such as acneiform eruption, xerosis, pruritus. There were 8 cases of SJS/TEN associated with EGFR-TKIs (Osimertinib, 4; afatinib, 2; gefitinib, 1; vandetanib, 1). SJS/TEN usually occurred from 20 to 50 days of administration. The earliest occurrence time was 8 days, the latest occurrence was 78 days. There were 3 cases of MKIs related SJS/TEN (Regorafenib, 1; Sorafenib, 1; apatinib, 1). The apatinib-related case was treated with the combination of Toripalimab. No death associated with EGFR-TKIs and MKIs related SJS/TEN was reported.

**Conclusions:** Compared with ICIS, EGFR-TKIs and MKIS related SJS/TEN is less common and mild, with well respond to steroid therapy and immunoglobulin and less deaths. It might be necessary to use anti-allergic agents before ICIs.

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## 34P RET-MAP: An international multi-center study on clinicopathologic features and treatment response in patients with NSCLC and RET fusions

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**Background:** Nearly 1-2% of patients (pts) with non-small cell lung cancer (NSCLC) harbour RET fusions and this rare population is not well characterized.

**Methods:** This retrospective multi-center study included pts from 17 European centres with any stage RET+ NSCLC. Molecular profile included DNA/RNA sequencing and/or FISH analyses. Clinical, pathological, biological features and treatment outcomes (assessed by investigators) including surgery, chemotherapy (CT), immunotherapy (ICI), CT-ICI, multityrosine kinase inhibitors (MTKi) and RET inhibitors (RETi) were evaluated.

**Results:** In 131 pts, median (m) age was 60 years, 57% were female, 92% had adenocarcinoma (5 NOS, 1 squamous, 2 large cell neuroendocrine, 2 atypical carcinoids). 44% had smoking history, 67% were metastatic at diagnosis including 19% with brain metastases (BM). At last follow up, 30% of pts had BM. RET fusions partners were KIF5B (71%), CCDC6 (20%), others (19%). mPD-L1 expression (n=101) was 5% (0-90), mTMB (n=18) was 3.50 (0-32) mut/mB. The most frequent co-mutation was TP53 (21%). The table reports treatment outcomes. Overall survival was higher in pts treated with RETi versus no RETi (2 lines: 62 vs 17.7 months, p=0.19; >2 lines: 53.5 vs 21.2 months, p=0.0087). Progression-free survival (PFS) under RETi was 16.23 vs 7.69 months in pts with and without TP53 mutations, respectively (p=0.43). In pts treated with single agent ICI, mPD-L1 was numerically higher in responders (CR/PR/SD $\geq$ 6 months, n=13) than in non-responders (SD<6 months/PD, n=19) (55% vs 0%, p=0.059) and mPFS was 12.91, 7.94 and 2.18 months in pts with PR, SD and PD as best objective response, respectively. ICI was permanently stopped in 3 pts for toxicity.

**Conclusions:** Pts with RET+ NSCLC may have a smoking history and heterogeneous histologies. RETi treatment improves survival in pretreated pts. ICI may be effective especially in pts with high PD-L1.

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**Table: 34P Outcomes by treatment**

| Stage | Early | Advanced | | | | | |
|---|---|---|---|---|---|---|---|
| First use of | Surgery N=31 | Double agent CT N=72 | Single agent CT N=23 | CT-ICI N=19 | ICI N=33 | MTKi N=15 | RETi N=87 |
| Median n. of line (range) | NA | 3 (2-4) | 5 (3-6) | 2 (1-2) | 4 (3-5) | 4 (3-6) | 2 (2-3) |
| ORR (N, %) | NA | 38/64 (59) | 5/18 (28) | 9/19 (47) | 10/31 (32) | 5/12 (42) | 57/77 (74) |
| mDFS/PFS (months, 95% CI) | 20 (13.4-29.3) | 8.71 (6.97-11-.8) | 2.99 (2.17-6.57) | 7.36 (3.88-NA) | 4.37 (2.76-11) | 3.88 (1.51-NA) | 17.1 (12.2-NA) |
| mDOR (months, 95% CI) | NA | 7.03 (5.13-12.5) | 3.81 (1.84-NA) | 10.6 (8.8 -NA) | 9.46 (8.74-NA) | 5.82 (1.84-NA) | 23.9 (12.3-NA) |

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## 35P Real-world treatment outcomes of amivantamab in pre-approval access (PAA) participants with advanced non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations (ex20ins)

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**Background:** Amivantamab, an epidermal growth factor receptor (EGFR)-MET bispecific antibody, is approved for the treatment of patients with advanced EGFR ex20ins NSCLC that progressed on or after platinum-based chemotherapy. We present initial real-world experience with amivantamab acquired through the global PAA program.

**Methods:** Patients who were eligible for PAA (NCT04599712) had EGFR ex20ins NSCLC that progressed after platinum-based chemotherapy. Amivantamab (1050 mg; 1400 mg for bodyweight $\geq$80 kg) was administered intravenously once weekly for the first 4-week cycle, then every 2 weeks thereafter. Investigator assessment of response, based on radiologic and clinical judgement, was provided at the time of drug re-supply and was optional.

**Results:** As of 29 Oct 2021, 218 patients had received treatment with amivantamab across 120 sites in 19 countries; 66% from Asia, 22% from Europe, 8% from North America, and 5% from South America. The median age was 62 years (range, 24—84), and the median number of prior lines was 2 (range, 1—9), with 63% of patients heavily-pretreated with $\geq$2 prior lines. At the time of data cutoff (median follow-up of 4 months), 139 patients (64%) remain on treatment. The safety profile was consistent with previously-reported safety at the recommended dose (Park K, JCO 2021;39:3391); no new safety signals were identified. Among 82 patients with response information available, 25 (30%) reported partial responses. Frequency and response by site of exon 20 insertion will be reported at the time of the meeting. Median time to treatment discontinuation (events include patients who did not request drug within 45 days from last supply; patients who transitioned to commercial amivantamab were treated as censored) was 5.2 months (95% CI, 4.2—not evaluable).

**Conclusions:** The real-world experience of amivantamab from the PAA program was consistent with that observed from the registrational clinical trial (NCT02609776). At the time of data cutoff, 64% of patients remain on treatment. Patients who entered the amivantamab PAA program were heavily-pretreated, underscoring the high unmet need for patients with EGFR ex20ins NSCLC.

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