**Oral session**

**O1 – 8 – 3**  
**Phase II study of erlotinib + onartuzumab as first-line treatment for patients with MET-positive and EGFR-mutant NSCLC**

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**Background:** MET, a receptor tyrosine kinase, and its ligand, hepatocyte growth factor (HGF), play a key role in cancer progression and prognosis. Onartuzumab is a recombinant humanized one-armed anti-MET monoclonal antibody that inhibits HGF-induced MET signaling without agonistic activity. Pre-clinical and clinical data suggest that MET and EGFR cooperate on multiple levels to drive tumor growth and survival. Thus we planned to explore erlotinib + onartuzumab for patients (pts) with MET-positive (MET+) and EGFR-mutant (EGFRmut) NSCLC. However, this study was terminated early due to the results of phase III study evaluating erlotinib + onartuzumab for second- or third-line treatment of MET+ NSCLC (OAM4971g, NCT01456325).

**Methods:** Pts with MET+ and EGFRmut NSCLC without previous chemotherapy were treated with erlotinib + onartuzumab until progressive disease or intolerable toxicity.

**Results:** 61 pts received study drugs. Median age, 67 years; ECOG PS 0/1, 31 (51%) / 30 (49%); Stage IIIIB/IV/recurrence, 2 (3%) / 43 (71%) / 16 (26%); MET-IHC 2/3, 53 (87%) / 8 (13%); exon 19 deletion / exon 21 L858R, 32 (53%) / 29 (48%). Median treatment duration was 134 days (1–332). Median progression-free survival (investigator assessment) was 8.5 months (95% CI: 6.8–12.4). Objective response rate was 68.9% (95% CI: 55.7–80.1) and disease control rate was 88.5% (95% CI: 77.8–95.3). Median overall survival was 15.6 months (95% CI: 15.6–ND). Common treatment-related adverse events (AEs) observed in ≥30% of pts were paronychia, acneiform eruption, stomatitis, diarrhea, xerosis cutis, peripheral edema, hypoalbuminemia, pruritus, rash, and appetite loss. Treatment-related AEs of grade ≥3 were observed in 36 pts (59%), with acneiform eruption and rash reported in ≥10% of pts. Exploratory analyses for relationships between efficacy and biomarkers are ongoing.

**Conclusions:** It was hard to evaluate the efficacy and safety of erlotinib + onartuzumab due to early termination of this study.