578 FEASIBILITY OF EFTILAGIMOD ALPHA (SOLUBLE LAG-3 PROTEIN) COMBINED WITH STANDARD-OF-CARE-THERAPY IN ADVANCED NON-SMALL-CELL LUNG CANCER (NSCLC) ADENOCARCINOMAS. INITIAL RESULTS FROM INSIGHT–003

[1]Akin Atmaca, [2]Daniel W Mueller, [1]Timursah Habibzade, [2]Marina Schaaf, [2]Jorge Klagges, [2]Regina Eickhoff, [1]Elke Jaeger, [2]Salah-Eddin Al-Batran, [1]Thorsten O Goetze*. [1]*Krankenhaus Nordwest, Frankfurt a.M., Germany*; [2]*Institut für Klinische Krebsforschung IKF am Krankenhaus Nordwest, Frankfurt a.M., Germany*

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Background Eftilagimod alpha (efti; IMP321) is a MHC II class agonist (soluble LAG-3 protein) which activates antigen-presenting cells followed by T-cell (CD4/CD8) activation. Data from the TACTI-002–trial (NCT03625323) and INSIGHT–004 of the current multiple-strata INSIGHT phase-I platform-study revealed that the combination of 30 mg efti subcutaneous (s.c.) with anti-PD-(L)1–checkpoint–inhibitor is well tolerated with encouraging efficacy especially in NSCLC. Stratum–C (INSIGHT-003) of the INSIGHT–study aims to evaluate the feasibility and tolerability of s.c. injections with efti combined with Standard-of-Care (SOC) chemo- and immuno-therapy in 1st-line NSCLC-patients (pts).

Methods In Stratum–C, pts with metastatic NSCLC adenocarcinomas are treated with: SOC–chemotherapy (carboplatin AUC5 / pemetrexed 500 mg/m^2 q3w for 4 cycles + 500 mg/m^2 q3w for maintenance) plus pembrolizumab 200 mg q3w combined with s.c. injections of efti (30 mg) (q2w for 24 weeks; thereafter q3w till week 52). Imaging is performed every 8 weeks and assessed locally. The primary endpoint is feasibility (defined by safety & tolerability) while secondary endpoints include objective response acc. to RECIST 1.1 and other efficacy parameters. In total 20 pts will be enrolled.

Results From 02Aug2021 till 22Jul2022, 14 pts have been enrolled. Median age is 66 years and 71.4% are male. Eleven (78.6 %) pts had PD-L1 TPS <50%. No occurrence of unacceptable toxicities (i.e., causally related to efti AND resulting in permanent discontinuation of combination-treatment before administration of two complete cycles). Two serious adverse events (1 thromboembolic event, grade 3; 1 bronchial infection grade, 3) were reported, both unrelated to efti. In total, 69 adverse events (grade 1-2: 29; grade 3: 38; grade 4: 2) were documented. The most frequent AEs were platelet-count decreased in three pts (21.4%, grade 1-3) and anemia (grade 2-3), white-blood-cell decreased (grade 3), and neutrophil-count decreased (grade 3-4) in four pts (28.6%). One grade 3 AE was considered related to efti (insomnia). 10/14 pts are currently evaluable for efficacy (four did not yet have any on-treatment tumor-staging): Seven (70 %) partial responses, two (20%) stable diseases, one (10%) progressive disease as best overall response acc to RECIST 1.1.

Conclusions To date, 30 mg efti combined with SOC appears to be feasible and safe with first promising signals of efficacy.

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Ethics Approval The study was approved by 'Ethik-Kommission bei der Landesärztekammer Hessen' institution's Ethics Board, approval number 2019-1267-fAM. Participants gave informed consent before taking part.

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