108TiP EMPOWER-lung 1: A randomized, open-label, multi-national, phase III trial of cemiplimab, a human PD-1 monoclonal antibody, versus chemotherapy in first-line treatment of advanced non-small cell lung cancer (NSCLC) with PD-L1 ≥50%

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Background: Most patients (pts) with NSCLC present with advanced disease at diagnosis. Systemic therapy with platinum-based doublet chemotherapy regimens has been the standard first-line treatment for pts with advanced NSCLC whose tumours do not have EGFR, ALK, or ROS 1 mutations, but there is a need for effective treatments to improve long-term survival. With the recognition that NSCLC tumours express PD-L1, checkpoint inhibitors are being investigated in several clinical trials. There is currently only one PD-1 inhibitor approved as monotherapy in first-line treatment of NSCLC with PD-L1 expression ≥50%. In a phase 1 dose escalation and NSCLC expansion cohort, cemiplimab (REGN2810), a human monoclonal anti-PD-1, has demonstrated antitumour activity with an acceptable safety profile in anti-PD-1 naïve, pretreated pts with NSCLC.

Trial design: This is a randomised (1:1), multicentre, open-label, phase 3 study of cemiplimab versus platinum-based doublet chemotherapy in systemic treatment-naïve pts (≥18 years) with stage IIIB, IIIC or IV squamous or non-squamous NSCLC whose tumours express PD-L1 in ≥ 50% of tumour cells (NCT03088540). Pts will be stratified by histology and geographic region. Pts will receive cemiplimab 350 mg every 3 weeks intravenously (for up to 108 weeks) or 4–6 cycles chemotherapy with (i) paclitaxel + cisplatin or carboplatin, (ii) pemetrexed + cisplatin or carboplatin with or without pemetrexed maintenance, (iii) or gemcitabine + cisplatin or carboplatin. The primary objective is to evaluate progression-free survival (PFS) as determined by blinded independent review committee. Key secondary objectives include assessment of overall survival and overall response rate. Assuming duration of study enrolment and follow-up of 28 months and 10 months, respectively, approximately 700 randomised pts are required to obtain 525 PFS events to yield approximately 90% power to detect a statistically significant change in median PFS between treatment arms, with the 2-sided type 1 error limited to 5%. An independent data monitoring committee will monitor safety data during study conduct.

Editorial acknowledgement: Medical writing support under the direction of the authors was provided by Emmanuel Ogunnowo, PhD, of Prime (Knutsford, UK) and funded by Regeneron Pharmaceuticals, Inc. and Sanofi according to Good Publication Practice guidelines.

Clinical trial identification: NCT03088540.

Legal entity responsible for the study: Regeneron Pharmaceutical Inc. and Sanofi.

Funding: Regeneron Pharmaceutical Inc. and Sanofi.

Disclosure: V. Sriuranpong: Honoraria for advisory board and institutional study support grants: Regeneron Pharmaceuticals, Inc. P. Clingan: Participation in clinical trial work: MSD, AbbVie and Checkpoint Therapeutics. N. Rizvi: Personal fees: Roche,

AstraZeneca, BMS, Merck, Novartis, Merck KGaA, Pfizer, outside the submitted work. O. Aren Frontera: Personal fees (advisory board & lecturing): Bristol Myers Squibb, Roche; Personal fees (lecturing): Novartis, outside the submitted work. S. Lee, S. Li, P. Snodgrass: Employee and shareholder: Regeneron Pharmaceuticals, Inc. P. Rietschel: Employee and shareholder, honoraria: Regeneron Pharmaceuticals, Inc. All other authors have declared no conflicts of interest.