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Editorial

Nanobytes

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IMMUNOTHERAPY BYTE

Newer molecules are bringing exciting alterations in therapeutic landscape of oncology. As immuno-oncology agents (IO) are securing their place in various settings in therapeutic landscape in oncology, more and more molecules are thronging the market. Cemiplimab is a new IO approved by the Food and Drug Administration for non-small cell lung cancer (NSCLC). On February 22, 2021, it was approved for the first-line treatment of patients with advanced NSCLC with high PD-L1 expression (tumor proportion score >50%) as determined by 22C3 assay, with no EGFR, ALK, or ROS1 aberrations. This approval is based on EMPOWER-Lung 1, an open-label, international, Phase 3 study, which recruited 710 smoker patients with histologically proven advanced NSCLC, who were randomly assigned (1:1) to cemiplimab 350 mg every 3 weeks or platinum-doublet chemotherapy. Crossover from chemotherapy to cemiplimab was allowed on disease progression. Primary endpoints were overall survival (OS) and progression-free survival (PFS) assessed by masked independent review committee. A median OS benefit of 7.8 months (22.1 months vs. 14.3 months, HR 0.68; $P = 0.0022$) and additional overall response rate of 16% (37% vs. 21%) was obtained in cemiplimab arm as compared to chemotherapy arm, in the intention-to-treat population (ITT). Median PFS was 6.2 months in the cemiplimab arm and 5.6 months in the chemotherapy arm (HR 0.59; $P < 0.0001$) in the ITT. The OS and PFS benefits were further enhanced in PD-L1 enriched subgroup (PD-L1 of at least 50%, $n = 563$), the HR for OS was 0.57 and for PFS was 0.54. The common adverse effects with cemiplimab were myalgia, rash, anemia, fatigue, anorexia, pneumonitis, and cough. The recommended cemiplimab dose for the treatment of NSCLC is 350 mg every 3 weeks, intravenously over 30 min.[1]

This is the third molecule approved in the same setting, after pembrolizumab and atezolizumab. Two peculiarities of this study are, all patients enrolled being smokers and 79% of them had PD-L1 of 50% or more. Final OS and PFS results and long-term data will shed further light on the clinical applicability of this drug, however, the available results look promising, in PD-L1 enriched population.

OPIUM CARCINOGENICITY BYTE

Opium is an illicit substance extracted from the poppy plant, specifically from the juice of the unripe seedpod, and contains multiple alkaloids. Contrary to the popular belief, compelling evidence is accumulating towards opium being carcinogenic to humans when smoked or ingested in various forms (e.g., raw, dross, or sap opium). As per Galveston cohort study of 50,045 subjects in Iran, regular opium use was associated with an increased, dose-dependent risk of developing laryngeal cancer. During a median 10 years of follow-up, 1833 participants were diagnosed with

cancer. For site-specific cancers, use of opium was associated with an increased risk of developing esophageal (HR 1.38), gastric (HR 1.36), lung (HR 2.21), bladder (HR 2.86), and laryngeal (HR 2.53) cancers in a dose-dependent manner (p_{trend}<0.05). Only high-dose opium use was associated with pancreatic cancer (HR 2·66). Ingestion of opium (but not smoking opium) was associated with brain (HR 2·15) and liver (HR 2.46) cancers. Of note, these data do not include other opiates such as heroin, morphine, codeine, or fentanyl.[2] Further studies are needed to look into the long-term safety of use of opiates in various clinical settings.

PHOSPHOINOSITIDE-3-KINASE (PI3K) BYTE

PI3K inhibitors are already known to have efficacy in relapsed chronic lymphocytic leukemia, follicular lymphoma, and breast cancer. Many patients with NSCLC are found to have targetable alterations in the PI3K pathway. This was demonstrated in a retrospective analysis of patients with NSCLC which identified potentially targetable alterations in PI3K pathway. These were not mutually exclusive to mutations in other pathways. These findings were presented at the European Lung Cancer Virtual Congress 2021. PI3K signaling pathway is implicated in both tumourigenesis and disease progression. Out of 479 patients with NSCLC who underwent NGS, 61 (12.7%) patients were identified as having an alteration in the PIK3 pathway. This alteration was identified by tissue-based NGS in 43 patients and by blood-based NGS in 19 patients. Most (57.3%) of the patients were metastatic at diagnosis, the 67% were male, and 87% were smokers. Most commonly occurring histologies were adenocarcinoma in 42% and squamous cell carcinoma in 36% of patients. Among study population, 27% had PD-L1-negative tumors. Out of 25 tested for tumor mutational burden, 52% had TMB >10 mutation/Mb.[3] Further clinical studies are needed to predict the potential clinical benefit from the use of PI3K inhibitors before it gets added to the oncologists armamentarium against NSCLC.

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