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Meeting Abstract: 2015 ASCO Annual Meeting I

FREE ACCESS Lung Cancer—Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers

May 20, 2015



Phase I/II study of nivolumab with or without ipilimumab for treatment of recurrent small cell lung cancer (SCLC): CA209-032.

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Background: Patients (pts) with SCLC respond to initial platinum (PLT) based chemotherapy (CT), but rapidly progress. Combined blockade of PD-1 and CTLA-4 immune checkpoint pathways has anti-tumor activity with a manageable safety profile. Nivolumab (NIVO) is a fully human IgG4 PD-1 immune checkpoint inhibitor approved in the US & Japan. Interim safety and efficacy of NIVO +\- ipilimumab (IPI), a CTLA-4 checkpoint inhibitor, in pretreated SCLC pts are reported. **Methods:** Pts who were PLT sensitive or refractory and had progressive disease were enrolled regardless of tumor PD-L1 status or number of prior CT regimens. This open-label study randomized pts to NIVO 3 mg/kg IV Q2W or NIVO+IPI (1 + 1 mg/kg, 1 + 3 mg/kg or 3 + 1 mg/kg) IV Q3W for 4 cycles followed by NIVO 3 mg/kg Q2W. Primary objective was overall response rate (ORR). Other objectives were safety, PFS, OS and biomarker analysis. **Results:** Seventy-five pts were enrolled (NIVO, n = 40; NIVO+IPI, n = 35); 59% had ≥ 2 prior regimens. Drug-related adverse events (DrAEs) in $\geq 10\%$ were fatigue (18%), diarrhea (13%), nausea (10%), and decreased appetite (10%) with NIVO; and fatigue (29%), diarrhea (17%), pruritus (14%), nausea, endocrine disorders and rash (11% each) with NIVO+IPI. Gr 3/4 DrAE in $\geq 5\%$ included diarrhea and rash (6% each; NIVO+IPI). Drug-related pneumonitis occurred in 2 pts (1 per arm). One pt experienced a drug-related SAE of myasthenia gravis on study which was fatal. Of 40 evaluable NIVO pts, partial response (PR) was seen in 6, 15% (duration of ongoing responses [DOR] 80-251+ days); stable disease (SD) in 9, 22.5%; and progressive disease (PD) in 25, 62.5%. In 20 evaluable NIVO+IPI pts, 1 had complete response (CR), 5% (DOR 322+ days); 4 had a PR, 20% (DOR 41-83+ days); 6 had SD, 30%, and 9 had PD, 45%. In the NIVO+IPI arm, 12 pts had not reached first tumor assessment and 3 were not evaluable. Nine pts (23%) continue treatment with NIVO and 19 (54%) with NIVO+IPI. **Conclusions:** In this PD-L1 unselected SCLC population with progression post-PLT, NIVO alone or combined with IPI was tolerable. ORR was 15% (NIVO) and 25% (NIVO+IPI) for evaluable pts; durable responses were noted. Updated safety, clinical activity and biomarker analysis will be presented. [Clinical trial information: NCT1928394.](#)

This is an ASCO Meeting Abstract from the 2015 ASCO Annual Meeting I. This abstract does not include a full text component.

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