LBA44 Lenvatinib (len) plus pembrolizumab (pembro) for advanced melanoma (MEL) that progressed on a PD-1 or PD-L1 inhibitor: Initial results of LEAP-004

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Background: Identification of safe and effective treatment options for MEL that progressed on anti−PD-1-based therapy is a large unmet need. The open-label, single-arm, phase 2 LEAP-004 study (NCT03776136) evaluates the combination of len (multikinase inhibitor) and pembro (anti−PD-1) in this population.

Methods: Eligible pts had unresectable stage III-IV MEL, PD confirmed per iRECIST within 12 wk of the last dose of a PD-1/L1 inhibitor given alone or with anti−CTLA-4 or other therapies for $\geq$2 doses, measurable disease, and ECOG PS 0/1. Pts received len 20 mg/d PO QD + $\leq$35 doses of pembro 200 mg IV Q3W until PD or unacceptable toxicity; eligible pts could be treated beyond PD. Imaging is done Q9W through wk 54, Q12W through wk 102, and Q24W thereafter. Primary end point is ORR per RECIST v1.1 by blinded independent central review (BICR). Secondary end points are PFS and DOR per RECIST v1.1 by BICR, OS, and safety.

Results: From Feb to Sep 2019, 103 pts were enrolled and treated; median age was 63 y, 67.0% had stage M1c/M1d disease, 55.3% had LDH >ULN (20.4% $\geq$2 $\times$ ULN), and 36.9% had BRAFV600 mutation. 61.2% received $\geq$2 prior therapies for MEL, 32.0% received prior BRAF $\pm$ MEK inhibition, and 28.2% had PD on prior anti−PD-1/L1 + anti−CTLA-4. Median study follow-up was 12.0 mo (range 8.7-15.6). Confirmed ORR by BICR was 21.4% (95% CI 13.9-30.5; 2 CRs, 20 PRs) overall and 31.0% (15.3-50.8; 1 CR, 8 PRs) for pts with PD on prior anti−PD-1/L1 + anti−CTLA-4. DCR was 65.0%. Median DOR was 6.3 mo (range 2.1+-11.1+); KM estimate of DOR $\geq$6 mo was 72.6%. Median (95% CI) PFS and OS were 4.2 mo (3.5-6.3) and 13.9 mo (95% CI 10.8-NR). 9-mo PFS and OS estimates were 26.2% and 65.4%. Most common treatment-related AEs (TRAEs) were hypertension (56.3%), diarrhea (35.9%), and nausea (34.0%). TRAEs were gr 3-5 in 44.7%, gr 5 in 1.0%, and led to discontinuation of len and/or pembro in 7.8%.

Conclusions: The combination of len and pembro has activity in pts with advanced MEL with confirmed progression on a PD-1/L1 inhibitor, including those with PD on combined anti−PD-1/L1 + anti−CTLA-4. The safety profile was consistent with prior studies. These data support len + pembro as a potential regimen for this population of high unmet need.

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LBA45 First report of efficacy and safety from the phase II study SECOMBIT (SEquential COMBo Immuno and Targeted therapy study)

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Background: Treatment of *BRAF*-mutated melanoma has dramatically changed with the introduction of targeted therapy (TT) and immune-checkpoint blockade (I-O). TT (encorafenib + binimetinib- E+B) has higher response rates, but these may be limited in duration. Conversely, I-O (ipilimumab + nivolumab — I+N) may have lower response rates, but more durable responses. Both treatments increase OS in metastatic melanoma patients. The question about which should be the first option is open. One strategy could be a short course of TT, switched to combo IO prior to progression of disease. In order to answer to this question, we conducted the SECOMBIT study, a randomized three-arms phase II study (NCT02631447).

Methods: From Nov 2016 to May 2019, n.251 patients with untreated, metastatic *BRAFV600* mutated melanoma, were enrolled at 37 centers in 9 countries. They were randomized 1:1:1 to Arm A [E+B until PD, followed by I+N], or Arm B (I+N until PD, followed by E+B) or Arm C (E+B for 8 weeks, followed by I+N until PD, followed by E+B). Patients received the treatments with the following schedules: TT, E 450mg p.o. daily + B 45mg p.o. bid; I-O, I 3mg/kg + N 1mg/kg Q3w x 4 cycles, followed by N 3mg/kg Q2w. Overall survival is the primary endpoint of the study. Secondary endpoints include total PFS, 2- and 3-years survival rate, best overall response rate, duration of response, biomarkers evaluation.

Results: 69 patients were treated in arm A, 71 in arm B and 69 in arm C. At a median follow-up of 17.5 months (IQR 10.2-23.4— d.b.lock July 2020), we report preliminary data of PFS, ORR and safety. mPFS was 15.8 months in Arm A, 7.2 months in Arm B, and 11.4 months in Arm C. In the 3 Arms 1-year PFS was 60%, 43% and 46% and 2-year PFS was 35%, 38% and 39% respectively. ORR was 82.6% (CR 21.7%) in Arm A, 45.1% (CR 15.5%) in Arm B and 78.3% (CR 29.0%) in Arm C. G3/4 toxicity was 49% in Arm A, 73% in Arm B and 51% in Arm C, while G.3/4 treatment-related adverse events were 28%, 54% and 32%. 18 pts were discontinued due to adverse events, 7 in Arm A, 8 in Arm B and 3 in Arm C.

Conclusions: At a minimum follow up of 1 year, our data confirm what reported in the pivotal studies. Despite the difference in term of mPFS, the 2-yrs PFS rate is similar among the different arms. The study is still ongoing for the completion of the main endpoint (OS).

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