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LBA16 IMpassion130: Final OS analysis from the pivotal phase III study of atezolizumab + nab-paclitaxel vs placebo + nab-paclitaxel in previously untreated locally advanced or metastatic triple-negative breast cancer

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Background: Based on findings from IMpassion130, international guidelines now recommend atezolizumab (A) + *nab*-paclitaxel (nP) for patients (pts) with locally advanced or metastatic TNBC (mTNBC) whose tumours express PD-L1 on tumour-infiltrating immune cells (IC). Here we report prespecified final OS and long-term safety results.

Methods: The study design and final PFS analysis have been reported (Schmid *NEJM* 2018). Pts were randomised 1:1 to A + nP or placebo (P) + nP. Co-primary endpoints were PFS (tested in parallel in ITT and PD-L1+ pts) and OS (tested hierarchically in ITT and, if significant, in PD-L1+ pts).

Results: As of 14 April 2020, 666/902 pts (73.8%) had died; median OS follow-up was 18.8 mo (IQR, 8.9-34.7 mo). 6% of pts in the A + nP arm and 2% in the P + nP arm remained on any treatment. OS data are in the Table. 460 A + nP arm pts and 430 P + nP arm pts were safety evaluable, of whom 8% and 3%, respectively, received nP for up to 24 mo. Similarly, 5% in the A + nP arm received nP for $\geq$ 24 mo (vs 1% in the P + nP arm). Respectively, 51% vs 43% had a G 3-4 AE; $\approx$ 1% per arm had a G 5 AE (no new G 5 AEs since last analysis; no patterns seen); 24% vs 19% had a serious AE, and 59% vs 42% had an AE of special interest (G 3-4 in 8% vs 5%). No confirmed or suspected COVID-19 AEs were reported. 19% in the A + nP arm and 8% in the P + nP arm had an AE leading to treatment discontinuation (most commonly due to neuropathy); in 18% and 8%, respectively, AEs led to nP discontinuation, and in 8% and 1%, AEs led to A or P discontinuation.

Conclusions: While OS differences for A + nP vs P + nP in the IMpassion130 ITT population were not statistically significant, precluding formal testing, clinically meaningful OS benefit was observed in PD-L1+ pts (7.5-mo median OS improvement). A + nP remained safe and tolerable with longer follow-up. Results from this final and mature OS analysis are consistent with prior interim analyses.

Clinical trial identification: NCT02425891.

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Table: LBA16

Final OS analysis	A + nP (n = 451)	P + nP (n = 451)
ITT population		
Events, n (%)	322 (71)	344 (76)
Median OS (95% CI), mo	21.0 (19.0, 23.4)	18.7 (16.9, 20.8)
Stratified OS HR[a] (95% CI); log-rank *P*	0.87 (0.75, 1.02); 0.0770[b]	
3-year OS (95% CI), %	28 (24, 32)	25 (21, 29)
PD-L1+ population[c]	(n = 185)	(n = 184)
Events, n (%)	120 (65)	139 (76)
Median OS (95% CI), mo	25.4 (19.6, 30.7)	17.9 (13.6, 20.3)
Stratified OS HR (95% CI)	0.67 (0.53, 0.86)[d]	
3-year OS (95% CI), %	36 (29, 43)	22 (16, 28)

[a] Stratification factors: prior taxane use, liver metastases, PD-L1 status. [b] Not significant [c] PD-L1 positivity defined as PD-L1—stained IC on $\geq$ 1% of the tumour area (VENTANA SP142 IHC assay) [d] Not formally tested per prespecified testing hierarchy.

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