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LBA34

Single-agent anti-PD-1 balstilimab or in combination with anti-CTLA-4 zalifrelimab for recurrent/metastatic (R/M) cervical cancer (CC): Preliminary results of two independent phase II trials

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Background

Second line treatment for R/M CC continues to be a high unmet clinical need. We present data from 2 ph2 trials, of single-agent balstilimab (bal) and in combination with zalifrelimab (zal) in R/M CC.

Methods

Patients received single-agent bal 3mg/kg q2w (NCT03104699) or in combination with zal 1mg/kg q6w (NCT03495882) up to 2 yrs. The primary endpoint was objective response rates (ORR) assessed per RECIST 1.1 by independent review, secondary endpoints included safety and DOR.

Results

We treated161 & 155 pts in the bal and bal/zal, respectively with 160 & 143 pts had baseline measurable disease (modified ITT population). All pts previously received platinum-based treatment for their first line as per protocol. Squamous-cell cancer (SCC) (63% bal; 74% bal/zal) was the predominant histologic subtype with adenocarcinoma/adenosquamous/other (AC) also represented. PD-L1 positive was defined as CPS ≥ 1% (62% bal; 55% bal/zal), negative as CPS <1% (26% bal; 25% bal/zal) or unknown (12% bal; 20% bal/zal). Efficacy data are below.

Treatment was well tolerated in both trials. 49 (30%) pts had immune-related AEs in bal & 50 (35%) in bal/zal trial (all grades) and severe (Grade 3+) 13 (8.0%) and 15 (10.5%) respectively. Treatment discontinuation were seen in 22 pts (13.7%) in bal and 15 pts (10%) in bal/zal. There were no treatment related deaths on the bal trial and 2 in the bal/zal trial (nephritis; pneumonitis). No new safety signals were identified.Table: LBA34

Efficacy	bal (160) N (%)	bal/zal (143) N (%)
ORR	24 (14)	31 (22)
CR	3 (2)	8 (6)
PR	20 (12)	23 (16)
DOR (m)	15.4 [1.1+,15.4]	NR [1.3+,16.6+]
SCC	18/100 (18)	28/106 (27)
AC	5/59 (8)	3/37 (7)
PD-L1 +	19/99 (19)	21/79 (27)

Efficacy	bal (160) N (%)	bal/zal (143) N (%)
PD-L1 -	4/42 (10)	4/36 (11)
Unknown PD-L1	0/19 (0)	6/28 (21)

Conclusions

These results show that both single-agent bal and bal/zal are active and well tolerated in R/M CC. Adding bal to zal increased both ORR and DOR with marginal increase in AEs. Responses were more common in the PD-L1 + and SCC pts, but responses were seen in PD-L1-, AC pts. This is by far the largest reported study of checkpoint inhibitors in cervical cancer to date.

Clinical trial identification

NCT03104699, NCT03495882.

Legal entity responsible for the study

Agenus Inc.

Funding

Agenus Inc.

Disclosure

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