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197P ATREZZO trial (SOLTI-1907): A phase II trial targeting estrogen receptor negative or PAM50 non-luminal disease with atezolizumab in combination with trastuzumab and vinorelbine in HER2-positive (HER2+) advanced breast cancer (ABC) - Interim analysis

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Background: Within HER2+ ABC, estrogen receptor (ER) negative or PAM50 non-luminal disease (HER2-enriched and Basal-like) are more immunogenic, have higher tumor-infiltrating lymphocytes and higher expression of immune-related genes. Here, we report the interim efficacy and safety data of the ATREZZO trial (NCT04759248).

Methods: ATREZZO is a single-arm, phase II trial evaluating atezolizumab, trastuzumab and vinorelbine combination in patients (pts) with HER2+, ER− or ER+ and PAM50 non-luminal subtypes ABC. Key inclusion criteria include progression to prior trastuzumab and antibody drug conjugate and presence of measurable disease. The primary endpoint was overall response rate (ORR). Tumor samples are mandatory to assess PAM50 and PD-L1 IHC (SP142) status. Based on a Simon's two stage design, the analysis of the first stage was planned after 19 evaluable pts, if at least 3 pts achieved an objective response, the trial would continue up to recruit 55 evaluable pts for a target ORR $\geq$ 13. The evaluable population was defined as all pts who had received at least one dose of treatment and had at least one postbaseline tumor assessment.

Results: 61 pts were pre-screened, and 42 ER+ and non-luminal or ER- tumors were identified. From these, 23 pts were recruited, and 19 were evaluable for primary endpoint. Baseline pts characteristics: median age 58 years (33-72), ER+ 32% (6/19), visceral disease 90% (17/19), median of 3 (1-4) prior lines for ABC and PD-L1 IHC tumors+ 16% (3/19). At the time of data cut-off (Feb, 2022), 14 pts had stopped their treatment because of PD and 1 due to toxicity. 4 pts were still on treatment. The ORR was 31.6% (6/19, 95% CI 12.59-56.57), meeting the pre-specified ORR for the stage I of the trial. 42.1% of patients (8/19) experienced grade 3-4 AEs.

Conclusions: The stage I of ATREZZO met its pre-specified endpoint. Completion of the stage II part of the trial with the inclusion of up to 55 pts is warranted to assess the activity of this combination in this group of pts. Correlative studies are ongoing and will be presented at the meeting.

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