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Lay Language Summary

ATRACTIB

Phase II clinical trial to evaluate the efficacy and safety of first line atezolizumab in combination with paclitaxel and bevacizumab in patients with advanced or metastasic triple-negative breast cancer

Context

Triple-negative breast cancer (TNBC) is a type of breast cancer characterized by the fact that the cancer cells don't have estrogen or progesterone receptors (Hormone Receptors) and do not have any or much of a protein called Human Epidermal Growth Factor Receptor-2. TNBC accounts for about 10 to 15% of all breast cancers. Patients with TNBC at advanced stage have poor survival and fewer treatment options available than other types of breast cancer. Atezolizumab, an antibody that blocks the programmed-cell death ligand-1 (PD-L1) protein, combined with the chemotherapy agent nab-paclitaxel, is approved in multiple countries as first-line treatment in TNBC patients that present with an overexpression of PD-L1 (PD-L1-positive patients) as it has demonstrated a clinical benefit in terms of progression-free survival (PFS), which means the length of time in which cancer does not get worse, and overall survival.

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Bevacizumab is an anti-angiogenic drug (a treatment that stops tumors from growing their own blood vessels, slowing their growth) in combination with paclitaxel has also demonstrated a sustained improvement in PFS, and is approved in Europe as the first treatment for metastatic TNBC.

About ATRACTIB and the patients

In the ATRACTIB phase II study we investigated the how effective is the combination of atezolizumab, bevacizumab, and paclitaxel in patients with advanced TNBC, regardless their level of the protein PDL1.

A total of 100 adult patients with untreated advanced TNBC were included in the study and received intravenous atezolizumab, bevacizumab and paclitaxel until disease progression, intolerable toxicity, death, or patient withdrawal. PD-L1 expression was assessed at the beginning of the study using immunohistochemistry. Tumor assessments were performed every 8 weeks for the first 12 months and every 12 weeks thereafter.

At the time of the analysis (15th September 2023), with a median follow-up of 16.7 months (range 1.1 - 34.1), the median PFS was 11 months, which means that 50% of patients had still not progressed at 11 months after treatment initiation. A total of 63 patients (63%) had a response to the treatment (13 and 50 patients with complete and partial responses, respectively), with a median duration of response of 10 months. The clinical benefit of the combination therapy was observed in 79% of patients.

Regarding safety, the most common secondary effects that emerged during the treatment were peripheral neuropathy (68%), a condition in which nerves in the hands, feet and arms are damaged and therefore causes pain and weakness, and fatigue (62%). Secondary effects attributed to treatment of grade 3/4 (those who required hospitalization or urgent medical intervention) occurred in 47% of patients, mainly peripheral neuropathy (13%) and neutropenia (12%), which is a decrease in white blood cells. There were no drug-related deaths.

Conclusions

In summary, the combination of the anti-PD-L1 atezolizumab plus bevacizumab added to chemotherapy as first-line treatment demonstrated encouraging antitumor activity in patients with advanced TNBC. Interestingly, most of them had PD-L1-negative tumors (97.6%). The observed PFS is much higher compared with that previously reported with other immunotherapy agents. The safety profile was consistent with the one previously observed with this combination, without significant added toxicity. These results merit further research of immunotherapy plus bevacizumab combinations for PD-L1-negative aTNBC patients.