

Triple-negative breast cancer patients who responded to immunotherapy had long-term survival benefit

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Among patients with metastatic triple-negative breast cancer (TNBC) who were treated with the anti-PD-L1 cancer immunotherapy atezolizumab (Tecentriq), those who responded to the medicine lived significantly longer (overall survival) compared with those who did not respond, according to data from a [phase I clinical trial](#) presented here at the AACR Annual Meeting 2017, April 1-5.

"Triple-negative [breast cancer](#) is an aggressive subtype of breast cancer often affecting younger women and, unfortunately, the current [treatment](#) options for metastatic disease remain limited," said Peter Schmid, MD, PhD, director of the St. Bartholomew's Breast Centre at St. Bartholomew's Hospital and Barts Cancer Institute in London.

This study involves the largest cohort of patients with [metastatic breast cancer](#) treated with immunotherapy to be presented to date, and it is the first study to report data on survival for this subgroup, according to Schmid.

"The most significant finding is the difference in the overall survival between patients who responded to atezolizumab and patients who did not respond. While all responders were alive after one year, the one-year survival rate for nonresponders was only 38 percent," Schmid said.

He added, "Another noteworthy finding is that metastatic TNBC patients

treated with atezolizumab had a prolonged median duration of response of 21 months, which is substantially longer than what has been seen with any other treatment to date for this patient population."

Schmid and colleagues recruited patients with metastatic TNBC to one of the expansion cohorts of the phase I trial. Of the 112 patients evaluable for response, 19 received atezolizumab as first-line treatment, and 93 had received at least two lines of prior therapy. At the time of enrollment, patients' tumors were evaluated for the presence of the PD-L1 (programmed death-ligand 1) protein on [immune cells](#) inside the tumor (tumor-infiltrating immune cells).

Patients belonged to one of two categories – those with PD-L1 on fewer than 5 percent of immune cells (IC0/1), and those with PD-L1 on 5 percent or more of immune cells (IC2/3) as assessed by an investigational immunohistochemistry test based on the SP142 antibody being developed by Roche Tissue Diagnostics.

Per [RECIST v1.1](#), 11 patients responded to treatment, for an overall response rate, which included complete and partial responses, of 10 percent.

Both one- and two-year overall survival (OS) rates for responders were 100 percent, and for nonresponders, OS rates were 33 percent and 11 percent, respectively. Of the 11 RECIST v1.1 responders, five received atezolizumab as first-line therapy, and nine had disease with high PD-L1 expression (IC2/3).

One- and two-year OS for patients who received atezolizumab as initial treatment (first-line) were 63 percent and 47 percent respectively; for those who were previously treated (second-line treatment or later), OS rates were 37 percent and 18 percent respectively. One-year OS for patients with high PD-L1 expression (IC2/3) was 45 percent, versus 37

percent for those with low to no PD-L1 expression (IC0/1).

Only 11 percent of patients experienced treatment-related grade 3 or 4 side effects, and side effects led to treatment discontinuation in 3 percent of patients, Schmid noted.

"Atezolizumab has yielded durable responses in a small population of both previously untreated and pre-treated TNBC patients and is associated with an excellent safety profile. The results provide further evidence that immunotherapy may play a significant role in the treatment of breast cancer," Schmid said. "It will be down to other ongoing and future studies to further improve on these treatment outcomes by optimizing treatment regimens and combinations for this hard-to-treat group of [patients](#)."

A limitation is that the study did not have a randomized control group with standard therapy; the survival data could therefore only been seen in the context of historical controls, Schmid said.

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