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Immunotherapy drug effective for metastatic triple negative breast cancer

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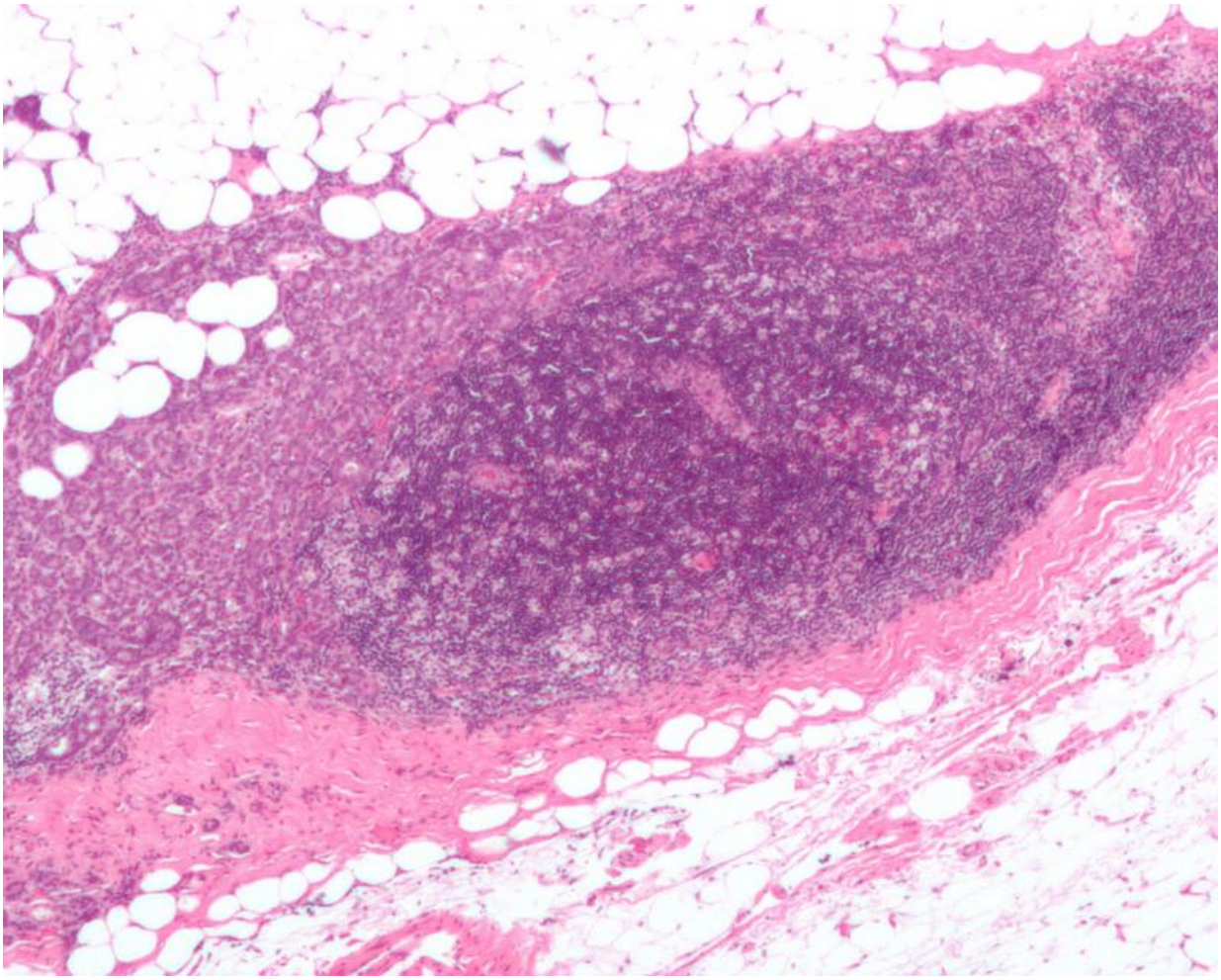

Micrograph showing a lymph node invaded by ductal breast carcinoma, with extension of the tumour beyond the lymph node. Credit: Nephron/Wikipedia

The immunotherapy drug pembrolizumab—already FDA-approved for other forms of cancer-has been found to be effective in patients with metastatic triple negative breast cancer, according to an international clinical trial led by NYU Langone's Perlmutter Cancer Center.

The trial investigated the drug in two separate cohorts of patients: Cohort A, which included 170 patients with heavily pretreated metastatic triple negative breast cancer (mTNBC) regardless of PD-L1 expression, and Cohort B, which included 52 patients with PD-L1-positive tumors who received it as first-line therapy.

In Cohort A, pembrolizumab shrunk tumors by more than 30 percent in eight of 170 patients, or five percent, and stabilized the disease in 35, or 21 percent, of those previously treated for mTNBC. Of the eight who experienced tumor reduction, all of them lived at least another year. The remaining patients in this cohort had a lower chance of survival.

In Cohort B—those who received pembrolizumab as first-line therapy—12 of 52 patients, or 23 percent, saw tumors shrink by more than 30 percent, while the disease was stabilized in nine of them, or 17 percent.

Sylvia Adams, MD, associate professor of medical oncology at Perlmutter Cancer Center and principal investigator of this study, presented the findings on June 3 in Chicago at the annual meeting of the American Society of Clinical Oncology. This multi-site trial was conducted at 17 medical centers across four continents.

Adams points out that Cohort A is the first phase II study of an immunotherapy for triple negative breast cancer to be reported and represents the largest cohort of patients with mTNBC treated with immunotherapy to date.

"Our results suggest that this treatment as a single agent is effective for mTNBC," Adams says. "Interestingly, we found that activity of pembrolizumab was seen in both PD-L1-positive and -negative tumors. These data are very encouraging, especially for a disease that is extremely aggressive and has limited treatment options when it metastasizes."

The goals of Cohort B, for which survival data are not yet complete, were, primarily, to prove pembrolizumab's safety and, secondarily, to explore its efficacy as a first-line treatment. Both goals appear to have been met.

"This research contributes to a larger body of knowledge that could help provide better outcomes to women with few treatment options," Adams adds. "The data also suggest that immunotherapy administered earlier in the disease course is more beneficial, as response rates are much greater in first- compared to second- or later lines of therapy."

Pembrolizumab, marketed under the name Keytruda, was well tolerated by both cohorts at a 200mg dose every three weeks, according to study results. Only 12 percent of patients in Cohort A experienced severe side effects and only eight percent experienced them in Cohort B. The most common side effects in both patient populations were fatigue and nausea. Although side effects led to discontinuation of treatment in seven patients from Cohort A, no patients in Cohort B discontinued treatment due to adverse side effects.

Triple negative breast cancer, which represents approximately 15 percent of all breast cancer diagnoses, is considered by many experts the most deadly form of the disease. Because it tests negatively for estrogen and progesterone receptors, it is unresponsive to hormonal therapies. Recurrence is common and often leads to metastases in other organs.

Currently, mTNBC is treated with chemotherapy, which is typically associated with significant toxicity and numerous side effects. Conversely, the side effects of pembrolizumab are much less frequent and more tolerable, says Adams.

Adams says more research is needed—such as identifying biomarkers, testing combination therapies and expanding clinical study to larger patient cohorts. Still, she is optimistic.

"Although only a small subset of women responded to the drug, within that subset pembrolizumab worked extremely well and responses were durable," Adams adds. "By causing fewer side effects and promoting longer life expectancy, pembrolizumab could help change the outcome of mTNBC."

Provided by New York University School of Medicine

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