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What Are the Data for TROP2-Targeted ADCs in HR+/HER2-Positive and HER2-Low MBC?

Announcer:
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Dr. Sammons:
Hello, my name is Dr. Sarah Sammons, and I'm Associate Director of the Metastatic Breast Cancer Program at Dana Farber Cancer Institute in Boston, Massachusetts. Thank you for joining me today to discuss the data for TROP2-targeting antibody drug conjugates in hormone receptor-positive and HER2-low breast cancer.

TROP2, or trophoblast cell surface antigen 2, is a glycoprotein that spans the epithelial membrane surface on many epithelial tumors. It is associated with tumor growth in a variety of tumors, and it is strongly expressed on nearly all subtypes of breast cancer. It is associated with poor prognosis and increased tumor growth in breast cancer as well as decreased survival.

Sacituzumab govitecan is the first FDA approved TROP2-targeting antibody drug conjugate. It is made up of three parts, which is a human anti-TROP2 antibody, a linker for SN-38 that has a very high drug-to-antibody ratio of about 7.6 to 1, and a pH-sensitive linker for rapid release of the payload at or inside the tumor. This is attached to a highly potent chemotherapeutic called SN-38. And this payload is able to deliver up to 130 times more of the parent compound than irinotecan itself, delivered systemically.

The TROPiCS-02 was the first phase 3 clinical trial to evaluate a TROP2 antibody drug conjugate, sacituzumab govitecan, in hormone receptor-positive HER2-negative or low breast cancer. Patients enrolled had to have progressed on at least 1 line of endocrine therapy, a CDK4/6 inhibitor, and a taxane. They could have at least 2 but no more than 4 lines of chemotherapy in the metastatic setting. So these patients were very heavily pretreated. They had to have measurable disease by RECIST. Five hundred and forty three patients were randomized 1 to 1 to receive sacituzumab govitecan or physician's choice endocrine therapy. The primary endpoint was progression-free survival.

The TROPiCS-02 phase 3 clinical trial enrolled the following patients with these characteristics, the majority of patients, 95%, had visceral metastasis, 84% of patients had liver metastasis. The median prior lines of chemotherapy in both arms was 3; therefore, these patients were very heavily pretreated and all had had a prior CDK4/6 inhibitor.

Here are the primary endpoint results for the TROPiCS-02 clinical trial showing that sacituzumab govitecan statistically significantly improved progression-free survival versus physician's choice chemotherapy, with a median progression-free survival of 5.5 months versus 4.0 months for a hazard ratio of 0.66. Interestingly, the 12-month progression-free survival rate was 21% with sacituzumab versus 7% with physician's choice chemotherapy.

Overall survival was also prolonged with sacituzumab versus physician's choice chemotherapy with a median overall survival of 14.4 months with sacituzumab versus 11.2 months with physician's choice chemotherapy.

The investigators also broke down sacituzumab efficacy in HER2-low, HER2-0 subgroups. This slide shows that sacituzumab was also effective over physician's choice chemotherapy in patients that were HER2-low or HER2-0.

Sacituzumab govitecan was approved by the FDA for hormone receptor-positive HER2-negative metastatic breast cancer on February 3, 2023, for patients who had received endocrine-based therapies and at least 2 additional lines of therapy. Patients must have received endocrine therapy and a CDK4/6 inhibitor and at least 2 lines of chemotherapy to be included. And this is the population that is most likely to benefit from the results that we know to date.

Thank you so much for joining me to learn and understand about sacituzumab govitecan in the treatment of hormone receptor-positive breast cancer.

Announcer:
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