**Transcript Details**
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/clinical-practice/oncology-hematology/additional-safey-data-from-tropion-breast02-and-study-design-of-tropion-breast06/49125/

**ReachMD**
www.reachmd.com
info@reachmd.com
(866) 423-7849

# Additional Safey Data From TROPION-Breast02 and Study Design of TROPION-Breast06

**Announcer:**
Welcome to DataPulse from San Antonio Breast Cancer Symposium 2025 on ReachMD. This activity, titled “Additional Safey Data From TROPION-Breast02 and Study Design of TROPION-Breast06” is provided by Global Learning Collaborative.

**Dr. Jhaveri:**
Hello from San Antonio Breast Cancer Symposium 2025 here in San Antonio, Texas. I'm Dr. Komal Jhaveri, and today I'm reviewing additional safety data from the TROPION-Breast02 trial. I'll also review the study design for the TROPION-Breast06 trial in hormone receptor-positive breast cancer.

So starting off with TROPION-Breast02. Now, this was a study that was really designed in the first-line metastatic setting for patients with triple-negative breast cancer. These were patients who are not eligible for PD-1 therapy or do not have PD-L1 positivity on their tumors. These patients were randomized to receiving datopotamab-deruxtecan, a TROP2-directed antibody-drug conjugate, compared to physician choice chemotherapy. That could be one of many choices, including taxanes, eribulin, carboplatin.

And what we looked at—or evaluated—was to look at dual primary endpoints of both progression-free survival and overall survival. And in fact, the primary results were presented by Dr. Rebecca Dent at the annual ESMO meeting, where we showed that the trial met its primary endpoint for both progression-free and overall survival. And in fact, when we look at the degree of benefit that we saw compared to the physician choice chemotherapy arm for both progression-free and overall survival, there was a 5-month increment from the control arm favoring datopotamab-deruxtecan.

Now, when we think about the safety data or the toxicity profile for datopotamab, we know the most common toxicities that we see are nausea, we see mucositis, we see some ocular side effects, and there could be some level of interstitial lung disease as well, although those rates are rather low with datopotamab-deruxtecan.

At San Antonio, we saw some additional data that was presented by Dr. Tiffany Traina. And here, we showed that with datopotamab, we predominantly see grade 1 or 2 adverse events which were treatment related. And while we had seen that the treatment-related grade 3 or higher were actually more than the control arm, when we looked at the exposure-adjusted grade 3 or higher adverse events, they end up being lower with datopotamab compared to the physician choice therapy arm, and the treatment discontinuation rates were also lower with datopotamab compared to the physician choice chemotherapy arm.

So what do these data mean for our patients in clinic? We already have sacituzumab govitecan approved for metastatic triple-negative breast cancer in the second-line and beyond setting. We also have approval for trastuzumab deruxtecan, which is a HER2 ADC, based on the analysis from the DESTINY-Breast04 trial. But I think we have seen this exciting data from the TROPION-Breast02 trial for datopotamab-deruxtecan, this TROP2 ADC that showed not only progression-free but overall survival benefit and a great safety profile. So we really look forward to offering our patients an antibody-drug conjugate, such as datopotamab, in the first-line metastatic setting.

Now what we've also seen at the San Antonio meeting beyond triple-negative breast cancer is the TROPION-Breast06 study, which is specifically for hormone receptor-positive metastatic disease. And I've been involved with the development of this study. Now, specifically, this is looking at chemotherapy-naïve settings. So these are patients who would have received their endocrine therapies for

hormone receptor-positive disease and, once deemed endocrine therapy refractory but are chemotherapy-naïve, have measurable disease, would then be offered datopotamab-deruxtecan at 6 mg/kg intravenously every 3 weeks.

The primary endpoint here is progression-free survival by RECIST criteria. Patients would be required to undergo a biopsy. Archival tissue would be okay if it was collected within 6 weeks. And we're specifically focusing on the group which has HER2 immunohistochemistry 0 by the ASCO/CAP definition, which includes the true 0 or some incomplete membrane staining which is ≤10%. So we're focusing on this particular group of patients in the TROPION-Breast06 study, because we know datopotamab is already approved in the second-line and beyond setting after one line of chemotherapy and endocrine therapy.

We have the data from the TROPION-Breast01 and its approval based on the progression-free survival benefit already. The idea is, can we see whether we can use this drug even in the chemotherapy-naïve setting and specifically look at the IHC 0 subset.

So from the San Antonio Breast Cancer Symposium 2025 meeting, I'm Dr. Komal Jhaveri, and thank you so much for listening today.

**Announcer:**
Thank you for listening to this DataPulse from San Antonio Breast Cancer Symposium 2025 on ReachMD. This activity is provided by Global Learning Collaborative. Thank you for listening.