

MEDSIR's ATRACTIB & DEBBRA clinical trials: Promising results to improve the lives of advanced breast cancer patients

The ATRACTIB trial showed significant antitumor activity through a combined therapy, and the DEBBRAH trial had a median overall survival of 13.3 months.

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-- MEDSIR, a global leader in oncology

research, today presented significant breakthroughs in the fight against aggressive breast cancer at the 46th San Antonio Breast Cancer Symposium (SABCS) that have the potential to transform the lives of breast cancer patients. The results from the [ATRACTIB](#) trial, focusing on advanced triple-negative breast cancer (TNBC), and DEBBRAH Cohort 5, centered on HER2[+] or HER2-Low advanced breast cancer with leptomeningeal carcinomatosis, offer new hope for patients with limited treatment alternatives.



ATRACTIB: Transforming the Landscape for TNBC Patients

This phase II clinical trial highlights the success of a combined therapy approach as a first-line treatment for advanced TNBC patients. Specifically, the combination of anti-PD-L1 atezolizumab and antiangiogenic bevacizumab with chemotherapy agent paclitaxel, demonstrated significant antitumor activity. This breakthrough holds particular significance since most of the patients included in this trial had PD-L1 negative tumors.

Dr. Maria Gion, Medical Oncologist at Ramón y Cajal University Hospital and first author of the study, presented the study's outcomes, revealing a median progression-free survival of 11 months—a substantial delay in cancer progression compared to previous data on similar patient populations—. Impressively, 63% of patients responded positively to the treatment, achieving 13 complete responses and 50 partial responses, with a median duration of response reaching 10 months. Notably, the clinical benefit was observed in 79% of patients.

In the trial, 100 adult patients with untreated advanced TNBC received intravenous atezolizumab, bevacizumab, and paclitaxel until disease progression, intolerable toxicity, death, or patient withdrawal. The safety considerations revealed that peripheral neuropathy (68%) and

fatigue (62%) were the most common side effects. Grade 3/4 adverse events, occurred in 47% of patients, primarily peripheral neuropathy (13%) and neutropenia (12%). Importantly, there were no drug-related deaths.

ABOUT ATRACTIB

The ATRACTIB phase II study explored a combined treatment approach for advanced triple-negative breast cancer (a type of breast cancer characterized by the fact that the cancer cells don't have estrogen or progesterone receptors, and do not have any or much of a protein called Human Epidermal Growth Factor Receptor-2). The trial evaluated the first-line therapy atezolizumab (an immunotherapy drug), bevacizumab (an antiangiogenic drug), and paclitaxel (a chemotherapy agent) in a cohort of 100 patients, regardless of their PD-L1 tumor expression. Primarily, the study looked at progression-free survival, or how long the disease remained stable. Secondly, it also assessed overall survival, response to treatment, and safety. The results were encouraging, showing that this combination treatment had a positive impact on advanced TNBC patients, even when tumors didn't express PD-L1. Additionally, the safety profile of the treatment was consistent with what was known from previous studies.

ABOUT DEBBRAH

The DEBBRAH phase II trial was designed to evaluate the efficacy and safety of trastuzumab deruxtecan in patients with HER2[+] and HER2-low advanced breast cancer (meaning that tumors were characterized by the presence of either high or low levels of HER2 protein) with a history of brain metastases and/or leptomeningeal carcinomatosis. Patients were enrolled into one of five cohorts based on the HER2 protein level and type of central nervous system involvement. At SABCS 2023, results of Cohort 5 were presented, which specifically included 7 patients with leptomeningeal carcinomatosis. The main objective for this cohort was to measure the overall survival, or amount of time from the start of the treatment until death from any cause. With a median follow-up of 12 months (range, 2.5-18.6), results showed that treatment with trastuzumab deruxtecan led to a remarkable median overall survival of 13.3 months, meeting the primary endpoint. Five (71.4%) patients experienced a prolonged stabilization of their disease for at least 24 weeks, and the median time before their disease worsened again (known as progression free survival), was 8.9 months.

ABOUT MEDSIR

Founded in 2012, MEDSIR works closely with its partners to drive innovation in oncology research. Based in Spain and the United States, the company manages all aspects of clinical trials, from study design to publication, utilizing a global network of experts and integrated technology to streamline the process.

The company offers proof-of-concept support and a strategic approach that helps research partners experience the best of both worlds from industry-based clinical research and

investigator-driven trials. To promote independent cancer research worldwide, MEDSIR has a strategic alliance with Oncoclínicas, the leading oncology group in Brazil with the greatest research potential in South America. Learn how MEDSIR brings ideas to life: www.medsir.org.

ABOUT SABCS

San Antonio Breast Cancer Symposium (SABCS), hosts about 10,000 clinicians and scientists from all over the world and is the largest and most prestigious scientific gathering on breast cancer research.

Sandra Ramos
LLYC
+1 786-590-1000
[email us here](#)

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