MEDSIR announces positive results from TUXEDO-3 trial of patritumab deruxtecan in patients with active brain metastases and leptomeningeal disease

MEDSIR, a leading international medical research company, announced the positive results of the TUXEDO-3 trial at the American Society of Clinical Oncology (ASCO) Annual Meeting 2025. This phase II study funded by Daiichi Sankyo and Merck, known as MSD outside of the United States and Canada, evaluates the efficacy and safety of patritumab deruxtecan (HER3-DXd) in patients with active brain metastases and leptomeningeal disease, serious complications associated with advanced stages of the cancer.

The TUXEDO-3 trial is the first study to evaluate the intracranial and extracranial efficacy and safety of a novel anti-cancer drug in patients with breast and lung cancer and active brain metastases, and leptomeningeal disease from solid tumors.

The study was carried out to evaluate HER3-DXd in patients with metastatic breast cancer (mBC) and advanced non-small cell lung cancer (aNSCLC) with active brain metastases, and patients with leptomeningeal disease from solid tumors. This is an antibody-drug conjugate to target HER3, a protein receptor found on the surface of cancer cells in brain metastases. HER3-DXd is an investigational agent consisting of a fully human anti-HER3 IgG1 monoclonal antibody attached to a number of topoisomerase I inhibitor payloads (an exatecan derivative, DXd) via tetrapeptide-based cleavable linkers. The DXd ADC Technology payload causes tumor DNA damage, killing cancer cells within and surrounding the tumor microenvironment.

The study showed promising results, which were presented today in an oral session. Results from the leptomeningeal cohort have been simultaneously published in the renowned journal Nature Medicine due to its potential benefit in patients with a high unmet medical need. In patients with breast cancer and brain metastases, intracranial responses were observed across all breast cancer subtypes, including luminal, HER2-positive, and triple-negative.

"This study represents a significant advancement in our understanding of how to treat brain metastases and leptomeningeal disease, and we are hopeful that our findings will pave the way for new, effective therapies for these patients," stated Dr. Matthias Preusser, Medical Oncologist and Head of the Clinical Division of Oncology, Medical University of Vienna and Principal Investigator of TUXEDO-3. Dr. Rupert Bartsch, Consultant Hematology and Medical Oncology, Medical University of Vienna, added: "Brain metastases and leptomeningeal disease represent severe complications in cancer, leading to increased morbidity and mortality, and HER3-DXd could be a promising therapeutic alternative for these patients."

MEDSIR's trial DEMETHER, an international, phase II trial exploring the maintenance of trastuzumab and pertuzumab following trastuzumab deruxtecan as induction treatment for HER2-positive recurrent metastatic breast cancer patients, was mentioned during today's Discussion of

LBA1008. DEMETHER's strategy is to optimize the sequence to increase patients' progression free survival (PFS) while improving their quality of life.

The relevance of this mention highlighted the ability of MEDSIR for anticipating patients' needs and designing strategical trials to keep on pushing the barriers of clinical research. MEDSIR active presence at the ASCO Annual Meeting 2025 reinforces its leadership in excellence-driven oncology research and highlights its focus on addressing unmet needs in cancer treatment, with the aim of not leaving any patient left behind.

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