



TUXEDO-3

Patritumab deruxtecan (HER3-DXd) in active brain metastases from metastatic breast and non-small cell lung cancers, and leptomeningeal disease from advanced solid tumors: The TUXEDO-3 phase II trial

IMPORTANT:

- The document contains the summary of a clinical trial, and its sole purpose is to communicate the results of it to the general public.
- This document is not intended to promote recruitment or provide medical advice.
- The results reflected in this document may contradict those of other trials.
- It is not recommended to make decisions based on the information collected in this document; it should always be consulted with a medical professional beforehand.

ABOUT THIS SUMMARY

SPONSOR: MEDICA SCIENTIA INNOVATION RESEARCH S.L.

TUMOR TYPE: Cohort 1: Metastatic breast cancer with brain metastases.
Cohort 2: Advanced non-small cell lung cancer with brain metastases.
Cohort 3: Metastatic solid tumors with leptomeningeal disease.

MEDICINE(S) STUDIED: Patritumab deruxtecan

DATES OF STUDY: Ongoing (recruiting patients)

TITLE OF THIS STUDY: Patritumab deruxtecan (HER3-DXd) in active brain metastases from metastatic breast and non-small cell lung cancers, and leptomeningeal disease from advanced solid tumors: The TUXEDO-3 phase II trial

DATE OF THIS REPORT: May 2024

STUDY FUNDER: Daiichi Sankyo

CLINICAL TRIALS.GOV: [NCT05865990](https://clinicaltrials.gov/ct2/show/study/NCT05865990)

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What was the purpose of this study?

Cancer is a disease in which normal cells grow and divide uncontrollably. Sometimes, cancer cells leave the original tumor site and invade other areas of the body, where new tumors are formed in a process known as ‘metastasis.’ Therefore, when cancer cells spread from their original tumor site to the brain, brain metastases (BM) are produced. BM affect many cancer patients and increase the risk of death, especially in those with metastatic breast cancer and advanced (or metastatic) non-small cell lung cancer (aNSCLC), two of the most common types of cancer.

Other metastatic cancer cells that are produced in the bones, tissues, or organs (called ‘metastatic solid tumors’) can also spread from their original site to the leptomeninges, which are thin tissue layers that cover the brain and the spinal cord. In this case, it produces leptomeningeal metastasis, also known as leptomeningeal disease (LMD).

To protect our brain from dangerous substances and avoid damage, there is a locked layer of cells called ‘blood-brain barrier.’ This set of cells is impenetrable for most drugs and, therefore, patients with BM and/or LMD have very limited treatment options. There is a group of treatments that have shown promising results and are called ‘antibody-drug conjugates’ (ADC).

An ADC is a type of targeted therapy that allows the delivery of a cytotoxic agent selectively to cancer cells, since it combines the cytotoxic effects together with the selectivity of the monoclonal antibody. ‘Human epidermal growth factor receptor 3’ (HER3), and its blockade by specific anticancer drugs could overcome cancer cell development.

What did researchers want to find out?

We hypothesize that patritumab deruxtecan (HER3-DXd) may be a promising anti-cancer therapy for patients in which the central nervous system is involved. HER3-DXd is an ADC made up of patritumab, which is an antibody that binds HER3, and deruxtecan, which is a topoisomerase I inhibitor, a drug that damages the DNA of cancer cells by blocking their cell cycle and producing cell death.

When and where did the studies take place?

The study is currently ongoing in Austria and Spain.

Who took part of this study?

A total of 60 patients will be recruited from Austrian and Spanish hospitals and will be treated with intravenous HER3-DXd once every 21 days, and will be divided into the following groups (20 patients each): (1) metastatic breast cancer with BM, (2) advanced non-small cell lung cancer with BM, and (3) metastatic solid tumors with LMD.

For further information: www.clinicaltrials.gov

What were the results of the study?

The efficacy and safety of HER3-DXd will be evaluated in cohort (1) and (2) by measuring the intracranial objective response rate, which is the percentage of patients with measurable intracranial disease (one or more brain lesions ≥ 10 mm) clinical responses to the treatment, and in cohort (3) by analyzing the 3-month overall survival, to know the percentage of patients who will be alive after 3 months of starting the treatment. The results will be considered positive if there are, at least, three patients with clinical responses in cohorts (1) and (2), and, at least, three patients alive in cohort (3).

What were the main medical conclusions?

TUXEDO-3 is the first clinical trial evaluating the efficacy and safety of HER3-DXd over time in patients with pretreated metastatic breast cancer and advanced non-small cell lung cancer with BM, and metastatic solid tumors with LDM. If positive, this study could streamline the introduction of HER3-DXd as a new treatment for these patients who currently have very limited therapeutic options.

Where I can find more information?

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

For more details, please visit:

<https://www.medsir.org/clinical-trials/tuxedo-3>

The full scientific report of this study is available online at:
www.clinicaltrials.gov

Thank you who took part in the study

If you took part in this study, **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co**, as the Sponsor, extends its gratitude for your participation. This overview will outline the findings of the study. If you have any queries regarding the study or its outcomes, please reach out to the doctor or staff at your study location.

About Oncoclínicas & CO

Oncoclínicas - the largest cancer care group in Latin America - has a specialized, innovative model that focuses on the entire oncology care process, combining operational efficiency, humanized service and high specialization, through a medical team made up of more than 2,600 professionals, who mainly specialize in oncology. With the mission of making cancer treatment accessible to everyone in the country, it offers a complete operational system made up of outpatient clinics integrated with highly complex oncology centers. It currently has 134 units in 35 Brazilian cities, providing access to cancer care in all regions where it operates, with the quality standards of the best cancer centers in the world.

Through technology, precision medicine and genomics, Oncoclínicas ensures effective results and facilitates access to oncology treatment and has performed more than 595,000 treatments in the last 12 months alone. It is the exclusive partner in Brazil of the Dana-Farber Cancer Institute, an affiliate of Harvard Medical School and one of the most prestigious cancer research and treatment centers in the world. The Group also owns Boston Lighthouse Innovation, a bioinformatics company based in Cambridge, USA, and holds shares in MEDSIR, a Spanish company dedicated to the development and management of clinical trials for independent cancer research. The company is also developing projects in collaboration with the Weizmann Institute of Science in Israel, one of the world's most prestigious multidisciplinary scientific and research institutions, whose international board includes Bruno Ferrari, founder and CEO of Oncoclínicas.

For further information: www.grupooncoclinicas.com

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