Lay Language Summary

PECATI

A phase 2 trial to evaluate the efficacy and safety of lenvatinib in combination with pembrolizumab in pretreated advanced B3-thymoma and thymic carcinoma

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:	Thymic Carcinoma
MEDICINE(S) STUDIED:	Pembrolizumab and lenvatinib
DATES OF STUDY:	From September 2021 to February 2024
TITLE OF THIS STUDY:	PECATI: A phase 2 trial to evaluate the efficacy and safety of lenvatinib in combination with pembrolizumab in pretreated advanced B3-thymoma and thymic carcinoma
DATE OF THIS REPORT:	July 2024
STUDY FUNDER:	MERCK SHARP & DOHME S.A.
CLINICAL TRIALS.GOV:	NCT04710628

The content for this document was finalised by **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co** on the 23rd of July of 2024. The information in this summary does not include additional information available after this date.

What was the purpose of this study?

Thymic epithelial tumours (TET) represent a group of rare, heterogeneous malignancies arising from thymic epithelial cells, and represent 50% of all anterior mediastinal masses. TET entities include thymomas (T) with subtypes (A, AB, B1, B2, B3) and aggressive thymic carcinomas (TC). In the European Union, the overall annual incidence of TET is 0.18 per 100.000 (T: 0.14/100.000, and TC: 0.01/100.000).

The optimal treatment for patients with platinum refractory advanced B3-Thymoma (T) and thymic carcinoma (TC) has not yet been established. Both lenvatinib (a multi-tyrosine kinase inhibitor with antiangiogenic properties) and pembrolizumab (an immune checkpoint blocker) have shown clinically meaningful results in this setting.

The combination of lenvatinib plus pembrolizumab has shown promising synergistic activity in solid tumors such as renal cell carcinoma and endometrial cancer. Therefore, the purpose of PECATI trial is to assess the efficacy and safety of lenvatinib plus pembrolizumab in patients with advanced pre-treated B3-T and TC without autoimmune disorders.

What did researchers want to find out?

Lenvatinib combined with pembrolizumab reported a 91% rate of 5-months progression-free survival in pre-treated advanced B3-thymoma and thymic carcinoma. Toxicity profile is manageable but close monitoring is advised.

When and where did the studies take place?

The trial is a multicentric study (Italy, France and Spain) that enrolled the first patient on 13/05/2022 and completed enrollment accrual on 01/02/2024.

What were the results of the study?

The study met its primary endpoint: 5-PFS rate of 91%, with 1-year PFS of 62%. The confirmed objective response rate (ORR) was 21% with a confirmed disease control rate (DCR) of 67%. The 1-year overall survival (OS) was 85%. The safety (grade ⩾3 treatment related adverse events, TRAEs) was 34.9%, being the most common diarrhea (7%), hypertension (7%), and hepatic cytolysis (5%). Serious grade ⩾3 TRAEs occurred in 16% of patients (7/43), including 1 (2.3%) patient with myocarditis, and 1 (2.3%) patient with pneumonitis. There were no treatment-related deaths.

What were the main medical conclusions?

Lenvatinib combined with pembrolizumab is a potential standard treatment in pre-treated advanced B3-thymoma and thymic carcinoma. Toxicity profile is manageable but close monitoring is advised.

What were the main social conclusions?

Lenvatinib combined with pembrolizumab could become a common treatment for advanced B3-thymoma and thymic carcinoma previously treated at least with one previous line of platinum-based chemotherapy. The side effects can be handled when patients are watched closely.

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/abigail-clinical-trial

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