Thermosome Announces Further Dose Escalation in Phase I Trial with Lead Program THE001

- *First dose level rated as safe by independent Data Safety Monitoring Board*
- *Second dose level to be administered according to plan*
- *THE001 designed as targeted tumor treatment independent of specific molecular targets or tumor subtypes*

Munich, Germany – February 6, 2024 – Thermosome, a drug development company specializing in targeted tumor therapies, today announced that it received clearance by the independent Data Safety Monitoring Board (DSMB) to proceed as planned with the dose escalation in its ongoing Phase I trial of its lead program THE001. The first dose level was safe and well tolerated as assessed by the DSMB.

The Phase I, open-label, interventional dose-escalation trial is enrolling patients with locally advanced unresectable or metastatic soft tissue sarcomas at two German clinical sites: Helios Klinikum Berlin-Buch and LMU Klinikum, Munich. THE001 is planned to be administered at three dose levels. The first dose level was 20mg/m^2, the second, recently initiated dose level is 40mg/m^2. Primary endpoints of the study are the safety and tolerability of THE001 and the determination of the maximum tolerated dose. A secondary objective is the evaluation of anti-tumor activity.

"This is an important milestone in our ongoing trial, and we are happy to have reached the second dose level according to plan," said Dr. Frank Hermann, MD, Chief Medical Officer (CMO) of Thermosome. "The independent Data Safety Monitoring Board has assessed that our lead candidate is safe and well tolerated at the first dose level. We are now looking forward to the results of the next dose level."

Prof. Dr. Peter Reichardt, Principal Investigator of the trial, Head, Department of Oncology and Palliative Care, and Director of the Cancer Center Berlin-Buch, added: "We are very pleased to see safety and tolerability of THE001 in the first patients. Soft tissue sarcomas are large invasive tumors that are difficult to treat and are associated with a very poor prognosis. The response rate with available therapies is less than 30%, leaving a huge unmet medical need. I am excited to take part in this promising effort to develop a safe and effective treatment for STS patients that today have a very poor prognosis."

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About Thermosome

Thermosome is a clinical-stage drug development company focused on targeted tumor therapy combined with immune stimulation for improved cancer therapy. At its core is a novel, proprietary tumor targeting approach that allows for significantly increased local drug concentrations and improved tumor penetration to achieve improved clinical treatment efficacy.

The first clinical indication for its lead drug candidate THE001 is soft tissue sarcoma, where the Company aims to improve the current standard of care (free doxorubicin). Thermosome's approach enables targeted tumor treatment independent of specific molecular targets and covers patient populations across all tumor subtypes. More information: www.thermosome.com

About THE001

Thermosome's clinical-stage lead drug candidate THE001 is a thermosensitive liposomal formulation of the chemotherapeutic drug doxorubicin ($DPPG_2$-TSL-DOX). It has a different mode of action than conventional liposomes. Thermosome's technology enables intravascular drug release initiated by a mild heat trigger using clinically established hyperthermia devices. This results in up to 15-fold higher local drug concentrations in the tumor and aims to improve clinical treatment efficacy by creating a local boost at the desired site of action. These high local concentrations, which also reach less well perfused areas, are intended to overcome drug resistance. This effect cannot be achieved by administration of conventional doxorubicin due to systemic toxicity. Thermosome intends to further enhance treatment efficacy through an additive immune response induced by regional hyperthermia. THE001 has potential for further development in other anthracycline-sensitive solid tumors, such as breast, bladder, and ovarian cancer.

About Soft Tissue Sarcomas (STS)

STS is an atypical tumor with a patient population that includes many young patients. Locally advanced STS (LA-STS) are large invasive tumors that are difficult or impossible to resect. Neoadjuvant therapy is used to shrink these tumors preoperatively to allow tumor surgery with curative intent. Free doxorubicin in combination with ifosfamide or dacarbazine has been the gold standard for neoadjuvant therapy of all chemo sensitive LA-STS for several decades. Guidelines also recommend combining DOX-based therapy with regional hyperthermia. However, with response rates of less than 30%, there is a significant unmet need for improved treatment options. Soft tissue sarcomas occur in more than 50 different subtypes, making biologic targeting more difficult than physically controlled targeting with the most active agent. THE001 has been granted European Orphan Drug Designation for STS.

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