Thermosome Announces First Patient Dosed in Phase I Trial with Lead Program THE001

- *Addressing high unmet medical need in locally advanced soft tissue sarcoma*
- *Targeted tumor treatment independent of specific molecular targets or tumor subtypes*

Munich, Germany – May 24, 2023 – Thermosome, a drug development company specializing in targeted tumor therapies, today announced that the first patient has been dosed in April 2023 in the ongoing Phase 1 trial of its lead program THE001. Additional patients will be enrolled following a 6-week monitoring period that includes two treatment cycles.

The trial will enroll patients with locally advanced unresectable or metastatic soft tissue sarcoma at two clinical sites in Germany: Helios Klinikum Berlin-Buch and LMU Klinikum, Munich. THE001 will be administered at three dose levels, with three to six patients treated at each dose level (3+3 design). The primary endpoints of the Phase 1, open-label, interventional, dose-escalation study are the safety and tolerability of THE001 and the determination of the maximum tolerated dose. A secondary objective is to evaluate anti-tumor activity.

"We are delighted that the first patient in our Phase I study has been dosed at LMU Klinikum," said Dr. Pascal Schweizer, co-founder, and CEO/CFO of Thermosome. "Thermosome has now reached a key corporate milestone by transitioning into a clinical-stage company. We are looking forward to the results of this first-in-human study."

PD Dr. Dorit Di Gioia, Principal Investigator at LMU Klinikum, added: "Locally advanced soft tissue sarcoma is a disease with a very high unmet medical need, especially when it comes to novel therapeutic options for the neoadjuvant treatment of patients with localized high-grade tumors. While standard doxorubicin-based chemotherapy has only a modest effect, THE001 in combination with regional hyperthermia can achieve up to 15-fold higher local doxorubicin concentrations. This offers significant potential to enhance the treatment efficacy of the tumor and to induce an immune response."

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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 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.

Company Contact
Thermosome GmbH
Am Klopferspitz 19
82152 Planegg/Martinsried
phone + 49 89 7167760 31
media@thermosome.com

Media Inquiries
akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64 / +49 30 23 63 27 68