

Thermosome Announces Participation in IMAGIO Consortium to Improve Cancer Treatment

- *IMAGIO consortium of clinical partners coordinated by Philips receives EUR 24 million grant from the Innovative Health Initiative (IHI) and additional funding from industry partners to support the research tracks*
- *Consortium aims to improve clinical outcomes through less invasive treatments for lung cancer, liver cancer and soft tissue sarcomas*

Munich, Germany – June 20, 2023 – Thermosome, a drug development company specializing in targeted tumor therapies, today announced its participation in the IMAGIO consortium set out to develop innovations in interventional oncology focused on lung cancer, liver cancer and soft tissue sarcomas (STS). The IMAGIO consortium, consisting of approximately 30 clinics, academic institutes, healthcare companies, and patient organizations, has been awarded a EUR 24 million grant from the Innovative Health Initiative, complemented by additional funding from industry partners to conduct research on less invasive cancer treatments.

Thermosome will receive EUR 1.3 million of funding and will participate in the work package "Multimodal MR-HIFU (Magnet Resonance-High Intensity Focused Ultrasound) enabled therapy for sarcoma", which will be carried out by a group of partners coordinated by Prof. Dr. Holger Grüll, Chair of Experimental Imaging and Image-Guided Therapy at the University Hospital of Cologne, Germany. Further participants in the work package are Profound Medical, Philips, Turku University Hospital, and Gremse IT.

As part of the work package, the University Hospital of Cologne will conduct an investigator-initiated trial (IIT) to demonstrate the feasibility of targeted doxorubicin administration to tumors in combination with the Sonalleve® MR-HIFU system (Profound Medical). The Sonalleve® MR-HIFU system consists of Profound's high intensity focused ultrasound system integrated into a Philips magnetic resonance imaging (MRI) device and allows focal heating of tumor tissue to hyperthermic temperatures. The objectives of the trial in soft tissue sarcoma patients will be the evaluation of the novel hyperthermia feature with respect to safety and performance, and tumor targeting following THE001 treatment in combination with the MR-HIFU technology. The trial will be conducted in the second half of the 4-year program, following animal studies of THE001 in combination with MR-HIFU.

"We are delighted to be part of the IMAGIO consortium, and we look forward to expanding our collaboration with the University Hospital of Cologne," said Dr. Pascal Schweizer, co-founder and CEO/CFO of Thermosome. "We have been working with Prof. Dr. Holger Grüll and his group since the inception of Thermosome, including a highly successful, joint predecessor program called *temperature-sensitive liposomes – low-intensity focused ultrasound* (TSL-LIFU) from 2016 to 2020 which was funded by the German Federal Ministry of Education and Research (BMBF). IMAGIO will

build on this project and also consider the results of our ongoing Phase I trial of THE001, which was initiated earlier this year."

"Based on more than a decade of experience with thermosensitive liposomes and MR-HIFU, I am convinced that Thermosome's innovative tumor targeting technology is best-in-class," said Prof. Dr. Holger Grüll. "It has always been the goal of my work to provide MR-HIFU-enabled hyperthermia for image-guided tumor targeting using temperature-sensitive liposomes. I strongly believe that this project will nicely integrate these components, paving the way for broader clinical use of this approach."

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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 (DPPG₂-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.

About the IMAGIO Consortium

The IMAGIO consortium - *IMaging and Advanced Guidance for workflow optimization in Interventional Oncology* - includes the following partners: Philips, UMC Utrecht, LUMC, University Hospital of Cologne, TU Delft, Radboudumc, Luxium Solutions, Flash Pathology, Vrije Universiteit Amsterdam, Profound Medical, Gremse-IT, Thermosome, MUMC+, Nederlandse Leverpatiënten Vereniging, Fondazione IRCCS Istituto Nazionale Dei Tumori, Eberhard Karls University Tübingen, European Cancer Patient Coalition, Stichting Longkanker Nederland, ImaginAb Inc., Pfizer Inc., Universiteit Twente, Nanovi, Turku University Hospital, SIOPE Europe, Janssen Pharmaceutica; and associated partners Eidgenössische Technische Hochschule Zürich and The Newcastle Upon Tyne Hospitals NHS Foundation Trust. The IMAGIO industry partners are members of [COCIR](#), [EFPIA](#), [EuropaBio](#) and [MedTech Europe](#).

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Disclaimer

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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