



OxSonics Therapeutics
(“OxSonics” or the “Company”)

First-in-human clinical data shows SonoTran® is safe and well-tolerated

Data presented at the European Symposium on Ultrasound Contrast Imaging also demonstrated consistent SonoTran® Particle activation

Recruitment underway for Delivery and Efficacy cohorts of Phase 1/2a proof of concept study

Oxford, UK – 23 January 2023 – OxSonics Therapeutics, a clinical-stage medtech company focused on transforming cancer treatment through SonoTran®, its proprietary ultrasound-based drug delivery platform, today announces that first-in-human clinical data demonstrated that SonoTran® is safe and well-tolerated, with consistent Particle activation observed and mapped using OxSonics’ proprietary “see-as-you-treat” technology. The clinical data was presented by Dr Jeffrey Rubasingham, an oncologist at Oxford University Hospitals NHS Trust, Churchill Hospital, and the background and pre-clinical research by Professor Coussios, Statutory Chair of Biomedical Engineering at the University of Oxford and Director of the Oxford Institute of Biomedical Engineering, at the 28th European Symposium on Ultrasound Contrast Imaging, 19-20 January 2023.

The data is part of an ongoing Phase 1/2a multicentre clinical investigation funded by the National Institute for Health Research (NIHR), where SonoTran® is being evaluated in patients with metastatic colorectal cancer (mCRC). SonoTran® is in clinical development to enhance the delivery and improve the efficacy of oncology drugs, particularly targeted biological therapies that struggle to penetrate tumors. It combines innovative Particles that are independently co-administered with an anti-cancer drug, which are then activated by a novel ultrasound device at the tumor site, creating a localised pumping effect that increases the delivery and penetration of the drug throughout the tumor.

Nine patients were enrolled in the Safety Cohort, of which the primary objective was to evaluate the safety and tolerability of SonoTran® at three different doses of Particles, (three patients per dose). SonoTran® was safe and well tolerated at all three dose levels, with no serious adverse events reported. Particle activation (i.e. the generation of the Particle expansion and collapse that causes the localised pumping effect) at each dose level was also assessed using the Company’s “see as you treat” passive acoustic mapping technology. Consistent Particle activation was observed and mapped at all three dose levels. Based on these results, the lowest Particle dose (200mg) was selected for use in the Delivery and Efficacy Cohorts of the study, which are now both recruiting patients.

The Delivery Cohort will assess how much SonoTran® can enhance the delivery of cetuximab and irinotecan into tumors in resectable mCRC patients and the Efficacy Cohort will evaluate SonoTran®’s ability to enhance tumor reduction when combined with standard of care first-line treatment (cetuximab and FOLFIRI), compared with the standard of care alone.

Dr Marianna Lalla, Chief Medical Officer, OxSonics, commented: *“We are delighted by our first-in-human clinical data, in which we see that SonoTran® is safe and well tolerated in patients. Pre-clinical data has shown that SonoTran® increases the tumour penetration of drugs, leading to reduced tumor size and increased survival, and we look forward to seeing if this is replicated in the clinic in the Delivery and Efficacy Cohorts.”*

Jérôme Marzinski, Chief Executive Officer, OxSonics, commented: *“This clinical data is an important milestone for OxSonics showing that SonoTran® is safe and well tolerated, as well as that the SonoTran® Particles were consistently activated at the lowest dose. We believe that this Particle activation will be able to translate to enhanced delivery of drugs into solid tumors and ultimately potentially transform cancer treatment.”*

For more information on how SonoTran® works, click [here](#).

Enquiries

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About OxSonics Therapeutics

OxSonics is a clinical-stage medtech company, transforming cancer treatment by harnessing its first-in-class, proprietary technology platform SonoTran® to enhance the delivery and improve the efficacy of oncology drugs.

Current oncology drugs are restricted by their poor ability to penetrate solid tumors.

SonoTran® is being developed to provide a step-change in the therapeutic index of the drugs without the development costs or delays associated with drug reformulation. It combines Particles that are co-administered independently with an anti-cancer drug, and activated by a novel ultrasound device, creating a localised pumping effect that increases the delivery and penetration of the anti-cancer drug throughout the tumor. SonoTran® is designed to increase the dose and distribution of anti-cancer agents within solid tumours, thereby increasing the efficacy and/or reducing the toxicity of these agents across the majority of the most challenging solid tumor cancers.

The approach has been specifically designed to fit seamlessly into existing oncology clinical workflows, and has the major advantage of enabling healthcare professionals to “see-as-they-treat” by providing visualisation on-screen and in real time.

SonoTran® is currently being evaluated in a phase 1/2a proof of concept clinical study in patients with metastatic colorectal cancer with liver metastases.

The SonoTran® drug delivery platform is based on ground-breaking technological advances, originally invented at the University of Oxford’s Institute of Biomedical Engineering.

OxSonics is based in Oxford in the UK.

For more information please visit: www.oxsonics.com

About the phase 1/2a SonoTran® proof of concept clinical study

SonoTran® is being evaluated in a phase 1/2a multicentre clinical investigation in patients with metastatic colorectal cancer (mCRC) funded by the National Institute for Health Research ([NIHR](#)).

The clinical investigation includes three patient cohorts to evaluate:

1. The safety of the SonoTran® Platform (“Safety Cohort”);
2. SonoTran®’s ability to enhance the delivery of cetuximab and irinotecan into tumors in resectable mCRC patients (“Delivery Cohort”); and
3. SonoTran®’s ability to enhance tumor response to standard of care first-line chemotherapy (cetuximab + FOLFIRI) in unresectable mCRC patients (“Efficacy Cohort”).

Cohorts 1, 2 and 3 will recruit patients at the Oxford Cancer Centre, Churchill Hospital, Oxford University Hospitals (OUH) NHS Foundation Trust. Cohort 2 will additionally recruit patients at the Queen Elizabeth Hospital, Birmingham (UHB) NHS Foundation Trust. The coordinating investigator of the whole trial and the OUH site

principal investigator is Professor Rachel Kerr (Department of Oncology, University of Oxford).

About the National Institute for Health Research (NIHR)

The mission of the National Institute for Health Research (NIHR) is to improve the health and wealth of the nation through research. We do this by:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK Aid from the UK government.

For more information please visit: www.nihr.ac.uk.