



MHRA Case Study Illustrates How MHRA & OxSonics Help Cancer Drugs Go The Extra Mile

London, UK – 15 January 2015 – The Medicines and Healthcare products Regulatory Agency (“MHRA”) has helped OxSonics take a big step towards developing a revolutionary generation of ultrasound devices which aim to enhance delivery of anti-cancer drugs deep into solid tumours.

OxSonics Limited (“OxSonics”) was established in July 2013 to develop and commercialise a range of medical devices including “SonoTran”, an innovative drug delivery platform. SonoTran has the capability to overcome one of the greatest challenges facing solid tumour cancer therapy by delivering drugs throughout tumour volumes including to those areas that lie farthest from blood vessels. SonoTran not only has the potential to be applied to any oncological drug class, but also crucially provides on-screen feedback to the clinician as to where and when drug delivery has taken place, in doing so maximizing the potential of complete tumour coverage.

A case study published by MHRA today illustrates how The Innovation Office at MHRA provided OxSonics with informal access to world-leading expertise. It is hoped that following clinical trials the approach will result in better health outcomes for people currently facing a terminal illness. The case study is shown below.

MHRA Director of Licensing, Dr Siu Ping Lam said: “Our experts have the knowledge and experience to helpfully support SMEs to develop their innovative products. As well as being a regulator, we are passionate about helping companies develop products that could benefit patients and improve public health. Through the MHRA Innovation Office and scientific advice service, we are able to offer information and guidance to help companies, large and small, navigate scientific and regulatory requirements effectively.”

The new Innovation Office at MHRA helped in a number of ways:

- Co-ordinating and facilitating an initial meeting to clarify the classification of the particles and the ultrasound hardware – this in turn ensured that OxSonics could work to the correct regulatory standards.
- Providing advice on the scientific and regulatory aspects of the toxicology studies in order to help OxSonics take their development forward.
- Offering the opportunity to hold a scientific advice meeting to review the planned pre-clinical toxicology protocols that would need to be in place in order to gain approval to start clinical investigations.

Dr Colin Story, CEO, OxSonics said: “MHRA’s Innovation Office is an excellent resource for companies working to develop innovative technologies. The support offered by the MHRA through its Innovation Office has been invaluable to OxSonics. The Innovation Office has helped us with product classification and defining pre-clinical studies and MHRA will continue to support us by providing informal access to world-leading expertise.” According to Dr Story, there are no similar devices either on the market or in development.

The case study:

Innovation

Supporting innovation in anti-cancer drug delivery

Winter 2014/15

The issue

OxSonics is developing a new generation of ultrasound devices with the aim of solving a major challenge that exists in the treatment of solid tumour cancer today - where penetration by anti-cancer drugs faces significant limitations, due to the unique anatomy of solid tumours.

OxSonics believes that its technology has the potential to overcome these limitations, enhancing delivery of anti-cancer drugs deep into solid tumours, including to those cells that lie farthest from blood vessels, which may lead to better efficacy of drugs.

This is achieved using a phenomenon known as "inertial cavitation" to actively "pump" drugs deep into and throughout solid tumour volumes.

In working to bring this technology to market, a central challenge for the OxSonics team was that their technology combined both well-understood and characterised ultrasound hardware with highly innovative injectable "sono-sensitive particles".

OxSonics needed to understand how to classify these particles and also how to perform pre-clinical toxicology studies in order to gain approval to commence clinical investigations.

"MHRA's Innovation Office is an excellent resource for companies working to develop innovative technologies. The support offered by the MHRA through its Innovation Office has been invaluable to OxSonics - a relatively young but rapidly growing company developing cutting edge technology. The Innovation Office has helped us with product classification and defining pre-clinical studies and MHRA will continue to support us by providing informal access to world-leading expertise."



Dr Colin Story, CEO, OxSonics Limited

How MHRA helped

OxSonics contacted the MHRA Innovation Office seeking access to knowledge and expertise that would help them successfully navigate current scientific and regulatory requirements.

MHRA helped OxSonics in a number of ways by:

- **Co-ordinating** and facilitating an initial meeting to clarify the classification of the particles and the ultrasound hardware - this in turn ensured that OxSonics could work to the correct regulatory standards.
- **Providing** advice on the scientific and regulatory aspects of the toxicology studies in order to help OxSonics take their development forward.
- **Offering** the opportunity to hold a scientific advice meeting to review the planned pre-clinical toxicology protocols that would need to be in place in order to gain approval to start clinical investigations.

The outcome

The technology OxSonics is developing has the potential to deliver a step-change in the efficacy of both existing and new anti-cancer drugs for a whole range of solid tumour cancers. Following clinical trials, it is hoped the approach can demonstrate an improvement in health outcomes for those who currently face a terminal illness.

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Dr Siu Ping Lam
Director of Licensing, MHRA

How can we help you?

Is your organisation developing innovative products or technologies? Get in touch with us at the beginning of your project - we provide access to knowledge, guidance and experience that could help your organisation progress its innovation: innovationoffice@mhra.gsi.gov.uk www.mhra.gov.uk/innovation



About OxSonics Limited

OxSonics was established in July 2013 to develop and commercialise ground-breaking advancements in the field of therapeutic ultrasound invented at the University of Oxford's Institute of Biomedical Engineering. OxSonics "SonoTran" drug delivery platform has the capability to overcome one of the greatest challenges facing solid tumour cancer therapy by delivering drugs throughout tumours, including to the areas that lie furthest from blood vessels. SonoTran can be applied to any cancer drug. A major benefit of OxSonics' technology is the ability to provide real-time on-screen feedback to the clinician as to where and when drug delivery is taking place. OxSonics is based in Oxford, UK. For more information please visit: www.oxsonics.com.

About the MHRA Innovation Office

The Innovation Office, launched in March 2013, is one of the ways MHRA supports the Prime Minister's Life Science's strategy. This strategy calls for the encouragement of life science industries as a future growth area for the country. It is designed to help companies overcome barriers and it creates incentives for the promotion of healthcare innovation. Please see link to the MHRA's innovation office for enquiries: www.mhra.gov.uk/innovation.

About the MHRA

The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. Underpinning all our work lies robust and fact-based judgments to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare Products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health. <http://www.mhra.gov.uk>.