



You are here: | [Home](#) | [Science](#)

## Cancer-fighting spheres go global

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Australian life sciences company Sirtex has developed a cancer treatment based around microscopically small irradiated beads. The company's SIR-Spheres have already improved the lives of many liver cancer sufferers and may ultimately subdue one of mankind's greatest killers, as well as having an impressive range of non-medical applications.

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[Science](#)



In the early 1980s an academic at the University of Western Australia called Dr Bruce Gray began researching the feasibility of using tiny, radiation-impregnated beads – microspheres, around one third the diameter of a human hair – to treat liver cancer. From those humble beginnings emerged Sirtex Medical Limited, a global life sciences company now valued at \$1.5 billion that promises to revolutionise the treatment of cancer, and potentially play a crucial role in the development of everything from propulsion systems for miniature satellites to a 'sunscreen' that repels radiation.

Dr Steve Jones who has been with the company since the beginning, now Global Head of Research & Development, points out that while the potential uses of the microspheres Sirtex developed have since multiplied, the initial focus of the company was improving the lot of those diagnosed with liver cancer.

"Several hundred thousand people are diagnosed with advanced liver cancer every year. There are few treatment options and most people are dead within a year of being diagnosed even if they undertake chemotherapy," Dr Jones notes. "Sirtex developed a therapy called Selective Internal Radiation Therapy (SIRT). It involves patients having millions of tiny irradiated resin microspheres, called SIR-Spheres microspheres, injected through a micro-catheter into their groin, at which point the blood flow causes them to lodge in the tumour."

To use a military metaphor, SIRT is a surgical strike as opposed to the carpet-bombing of chemotherapy. It's a one-off treatment that only takes about 30 minutes and is usually done on an outpatient basis. The SIR-Spheres can contain up to 40 times as much (tumour-attacking) radiation as can be delivered externally through chemotherapy but despite that the patient doesn't have to deal with hair loss or nausea, though they may experience flu-like symptoms. Sirtex has invested \$60 million over five years to conduct large-scale clinical trials. Currently available clinical evidence suggests SIRT may approximately double the rate of tumour shrinkage and remission and improve life expectancy by 35-100 per cent compared to standard treatments.

There are now 45,000 people in 30 countries who've undergone SIRT treatment but the Sirtex story may have been very different if not for Australia's regulatory authorities and its abundance of world-class medical researchers.

"You need approval from the relevant authorities to test new treatments. Sirtex found there was a reasonably favourable regulatory regime in Australia, which probably reflects a culture that is comfortable with risk-taking innovation. Certainly, subsequently getting regulatory approval in other countries has proved far more time-consuming," notes Dr Jones.

SIRT can be used alone or in conjunction with other treatments. "You can have SIRT along with chemotherapy and we're working with [French pharmaceutical multinational] Guerbet to determine if a treatment they've developed - Lipiodol Ultra Fluid – can be combined or sequenced with SIR-Spheres to better treat hepatocellular carcinoma, metastatic colorectal cancer, metastatic neuroendocrine tumours, and other primary and secondary liver cancers," says Dr Jones.

The Guerbet collaboration is just one of many Sirtex is now involved in, with the company having established strategic research

partnerships with the Australian National University, Oxford University, Sydney University, the Peter MacCallum Cancer Institute, the Otto von Guericke University Magdeburg and the National Cancer Centre in Singapore. Space doesn't permit any but the briefest summary of Sirtex's current projects but its involvement in efforts to create a type of 'radiation sunscreen', a propulsion system for miniature satellites and treatments for a range of cancers gives some idea of the scope of its ambitions.

With more than ten different kinds of radioprotectors currently clinically available Sirtex has partnered with the Peter MacCallum Cancer Centre in Melbourne in order to develop a novel radioprotector compound. "A licensing agreement between the Peter MacCallum Cancer Centre in Melbourne and Sirtex Medical is supporting the develop of new radioprotectors, drugs that make cells less sensitive to ionising radiation, for example, X-rays," says the Centre's Professor Roger Martin.

"The focus of the research is development of radioprotectors that can be applied topically to normal tissues that are at risk in cancer radiotherapy patients. For example, for patients with tumours in the head and neck region, radiation-induced oral mucositis can be a serious problem. This could be prevented by topical application, in the form a spray, for example, of a radioprotector prior to radiotherapy treatment. Radioprotectors administered systemically also have many potential applications outside the cancer radiotherapy arena."

Understandably, those potential applications have attracted widespread interest from organisations such as the US Defence department, which are interested in using radioprotectors to protect military personnel and civilians from radiation exposure.

The microspheres Sirtex has developed are also useful in creating 'ferrofluid', a form of propulsion that can be used to push mobile-phone-sized nano-satellites in space that are increasingly being used by governments and private companies.

And it's not just liver cancer that can be treated with SIR-Spheres. "Liver cancer lends itself to SIRT because the way the blood flows around that area means that the SIR-Spheres will be delivered to the right; unfortunately things get a lot more complicated in other parts of the body," notes Dr Jones. "But we're already working on treatments for kidney and colorectal cancer and our researchers are thinking about how the SIR-Spheres could be delivered to cancerous tumours where there is no blood flow to deliver them there."

While Dr Jones is quick to point out that not all the research Sirtex is involved in will prove fruitful, he readily concedes his organisation has long since outgrown its start-up phase. It has won multiple awards such as the 2014 Frost & Sullivan Life Science Company of the Year and 2013 NSW Premier's Export Award for Health & Biotechnology with its chief executive Gilman Wong winning CEO magazine's CEO of the Year in 2012. It now has production facilities pumping out SIR-Spheres in the USA, Germany and Singapore and will triple its manufacturing capacity in 2015.

"The turning point for me was when we got FDA approval in 2002 to market our treatment in the USA," says Dr Jones. "That put us in an elite group of Australian companies, such as ResMed and Cochlear, that were operating in the US. The next big inflection point, aside from getting regulatory approval for markets such as Japan and China, will be when the results of the large-scale clinical trials come back. Hopefully they will provide the evidence to convince oncologists to make wider use of SIRT. Presently only around one per cent of liver cancer patients are given the treatment and it's often used a last resort rather than first option. Also, as personalised medicine technology develops, we should be able to much more precisely determine the dosages patients should receive."

Sirtex has always been circumspect about suggesting it is on the path to developing a cure for cancer. Nonetheless, the company's CEO Gilman Wong has now begun trumpeting his team's determination to help take the sting out of one of mankind's greatest scourges.

In a recent speech Wong declared, "Together with our customers and collaborators in the medical community, Sirtex shares a common vision where cancer is a treatable chronic condition that patients can successfully live with or be cured from. It is an ambitious goal but one for which there are many precedents. Diseases like HIV, diabetes and heart disease were all considered terminal conditions a few decades ago. Advances in medicine have seen these conditions become chronic conditions people can successfully live with."