

# Interest builds in Viralytics' cancer treatment

SARAH-JANE TASKER, THE AUSTRALIAN 12:00AM August 1, 2017

A lab experiment with a common cold virus and melanoma cells is behind one of the most exciting cancer discoveries made in Australia, and unassuming Newcastle scientist Darren Shafren is the man behind that success story.

A recent visit to the Memorial Sloan Kettering Cancer Centre in New York, the world's oldest and largest private cancer centre, was the moment Dr Shafren realised how far he had come.

"A clinician at the centre was asking me about the most effective way to treat a patient ... I was thinking I'm just a country boy from Newcastle," he said.

Dr Shafren is the chief science officer and inventor of technology at Viralytics, the Australian listed company that is commercialising his discovery. The company's lead drug is Cavatak, which is described as an - investigational novel cancer immunotherapy that is based on a common cold virus and has been shown to preferentially infect and attack cancer cells.

Melanoma is the main target but the company is also focused on bladder and lung cancers.

Dr Shafren completed his PhD in Newcastle and says it was the 1989 earthquake in that coastal city north of Sydney that encouraged him to leave his home town, putting him on the path to study viruses.

"The earthquake was probably a sign I should get out of Newcastle ... a couple of months after that earthquake I went to England and started a postdoctorate," he says.

He was offered a list of projects to consider for his postdoctorate, so he asked which one was the hardest. When told it concerned virus receptors, he put his hand up.

Dr Shafren, speaking to *The Australian* during a tour of Viralytics' laboratory in the Hunter Medical Research Institute in Newcastle, said he took his new expertise in viruses back to Newcastle and it was there that he crossed paths with a team looking at cancer.

He was once focused on trying to prevent viruses infecting patients but he slowly started to switch his thinking to examining whether the common cold virus could kill cancer cells.

It wasn't at first obvious what his team had stumbled upon when its research widened to include cancer cells. Dr Shafren, who leads a group of 12 scientists and research personnel, recalls asking one of his team to put the virus it was working on on to melanoma cells.

He called his team from a Sydney conference he was attending to be told the experiment had not worked as there had been contamination in the lab, so he told his team to retry. When he called back two days later he was told there had again been a contamination issue.

“It turned out that the virus was so good at killing the cells, it wasn't the contamination we were seeing, it was the dead tumour cells that were fragmented,” he says.

“We were no longer looking at how viruses infected cells so we could limit the infection; we were now looking at the virus to do something else.”

Initial studies were done in the late 1990s and early 2000s. Then Dr Shafren and his team progressed from laboratory cultures to small animal studies.

The University of Newcastle's commercial arm attracted some funding to allow the team to progress its early findings and Viralytics was eventually formed.

The first patient was dosed in Newcastle in 2004 but it wasn't until 2010, when the US regulator, the Food and Drug Administration, approved Viralytics' investigational new drug application, that momentum around the discovery started to build.

“The pivotal thing was getting the IND application. It gave you your driver's licence to get to the US and to be more visible in front of not only investors but pharmaceutical companies,” Dr Shafren said.

That green light kicked off the study the company needed — 60 patients receiving multiple doses of viruses into multiple cancer deposits in melanoma.

“It was a big thing. A lot of Australian biotechs are reluctant to go to the FDA because they have a 'good look under the skirt',” Dr Shafren said.

He said the study showed that the virus was not only affecting the lesions it was injected into but it was also stimulating the body's immune system.

“That was when it started to get interesting,” said Dr Shafren, who has over 20 years experience in basic and molecular virology.

He said the timing was perfect for Viralytics because just as it was moving into the space there was a quantum change in the way people were looking at treating cancers. “There was always the standard radiation, chemotherapy and surgery but there was a renaissance of immunotherapy treatments in the late 2000s,” Dr Shafren said.

It was around that time that common cancer drugs, Yervoy and Keytruda, were licensed. Viralytics is now testing its drug in combination with these two common immunotherapies.

“Immunotherapy was added as another arm in cancer treatment and we were fortunate to be at the right place at the right time,” Dr Shafren said.

“It's now about what is the best combination you can give a patient.”

The company knew it had found its place in a competitive field when it was invited to present at the American Association of Cancer Research's conference in Washington DC earlier this year. “The studies still need to be confirmed but we are seeing activity and that was translated at the conference in Washington earlier this year,” Dr Shafren said.

“It was at that conference that you sit back and think ‘we've gone all right’. Not many Australian biotechs get to do that in this particular space.”

The virus expert has not met any of the patients his research has already helped, which he says is one of the frustrating aspects of his role.

“I would like to meet them and sit down and have a beer with them, but we have to be at arms' length from everything,” he said.

“I have always been in it for the patients. When you can see what you have worked for translate into a favourable clinical outcome for a patient, that's how I measure success.”

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