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Kidney Cancer Update

Sirtex is pleased to provide an update on the Company's RESIRT clinical study of SIR-Spheres microspheres[®] for the treatment of renal cell carcinoma (RCC), the main type of cancer affecting the kidney.

The RESIRT study is a first-in-human study that aims to determine how high a radiation dose can be delivered to RCC using SIR-Spheres microspheres. A secondary aim of the study is to determine the potential effectiveness of SIR-Spheres microspheres in treating RCC.

The study seeks to recruit three patients at each of four successively higher radiation dose levels. Recruitment of patients at the highest radiation dose level (200Gy) has now been completed. No toxicity related to SIR-Spheres microspheres has been reported in any of the 12 study patients, including the three patients treated at the highest radiation dose level.

Given the absence of any toxicity at the highest radiation dose level, Sirtex will now expand the RESIRT study to recruit additional patients at higher radiation dose levels beyond 200Gy. The objective of expanding the RESIRT study is to fully define the optimum radiation dose, prior to launching a pivotal study of SIR-Spheres microspheres for the treatment of RCC.

Professor Paul de Souza, University of Western Sydney Foundation Professor in Medical Oncology and RESIRT study principal investigator said "The RESIRT study is the first study in the world using SIR-Spheres to treat cancers outside the liver. While some of our patients have experienced encouraging tumour control, we haven't seen any toxicity from treatment. We now need to examine additional higher radiation dose levels and look forward to defining the optimum radiation dose to take forward into a definitive trial."

In 2012, approximately 3,500 Australians and 58,000 Americans were diagnosed with kidney cancer. Over the past 20 years there has been a five-fold increase in the incidence of kidney cancer and a two-fold increase in mortality. While surgery is presently the main treatment for earlier stages of kidney cancer, advanced kidney cancer carries a poor prognosis. A significant unmet need exists among patients who are not able to undergo surgery or who have advanced stage disease that is not addressable via surgery.

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