



ASX Announcement

9th October 2014

Clinical Studies Update

Sirtex is pleased to provide an update on the Company's clinical studies of SIR-Spheres microspheres in patients with inoperable liver cancer.

SIRFLOX Study

The SIRFLOX study is an international multi-centre randomised controlled trial being carried out in Australia, New Zealand, the United States of America, Europe and Israel, and is led by leading independent medical oncologists Professor Peter Gibbs from Royal Melbourne Hospital, Melbourne, Victoria and Professor Guy van Hazel from Sir Charles Gairdner Hospital, Perth, Western Australia.

Sirtex completed patient recruitment for the SIRFLOX study in April 2013, with a total of over 500 patients. The completion of patient recruitment required the participation of more than 100 leading hospitals globally, and the utilisation of considerable resources over more than six years.

The SIRFLOX study aims to evaluate whether a first-line treatment strategy of using the current standard-of-care chemotherapy plus SIR-Spheres microspheres is more effective than chemotherapy alone, in patients with inoperable liver metastases from primary colorectal cancer (bowel cancer).

The primary endpoint for the SIRFLOX study is progression-free survival. Progression-free survival is a measure of the remission effect of the treatment (i.e. the time interval from randomisation until tumour progression). There are also a number of secondary endpoints being assessed in the study (including overall survival, tumour response rate, quality of life and surgical resection rate).

Further details regarding the SIRFLOX study have previously been announced by the Company, including in its original announcement on 18th October 2007, and more recently in its announcement on 8th May 2014.

The SIRFLOX study has now been concluded. The final reconciliation of the study database has therefore commenced. That reconciliation will involve an initial analysis of the study background and the safety data, and an ongoing verification of the data. It is expected that this process will be completed by mid March 2015, and that the database for the SIRFLOX study will be complete and will be finally locked on that date.

Once the database has been locked, the data will be analysed to establish whether the primary endpoint of the SIRFLOX study has been reached. It is presently anticipated that this will take up to 7 days and will be completed in around the third week of March 2015. A further

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announcement will be made by Sirtex at that time as to whether the primary endpoint of the SIRFLOX study is believed to have been reached.

After that time, the study results and preliminary analysis will have to be verified and validated.

Peer review, through publication in a medical journal or presentation at a scientific conference, is an essential part of the verification and validation process. It is expected that the final results and related detailed analysis of the SIRFLOX study will be submitted to and presented at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago in June 2015.

The ASX and AusBiotech Code of Best Practice for Reporting by Life Science Companies recognises the importance of peer review in the validation process.

If the results from the SIRFLOX study are then confirmed as positive, Sirtex believes that SIR-Spheres microspheres may be elevated to a first-line therapy for patients with colorectal liver metastases, providing important clinical benefits to patients and leading to a material change in Sirtex's business. On the other hand, if the results from the SIRFLOX study are not confirmed as positive, Sirtex believes that SIR-Spheres microspheres will remain a salvage therapy for the foreseeable future.

Until the final results and analysis of the SIRFLOX study are accepted and presented at the ASCO Annual Meeting they remain unvalidated.

FOXFIRE Global Study

As previously announced by the Company, the FOXFIRE Global study is scheduled to complete recruitment during the first quarter of calendar year 2015 (Q1 C2015).

Due to a high level of interest in the FOXFIRE Global study at participating hospitals, patient recruitment has accelerated during 2014 and is well ahead of schedule. Sirtex intends to complete patient recruitment to the FOXFIRE Global study during Q1 C2015 as scheduled. However, due to the accelerated rate of patient recruitment the total number of patients on the FOXFIRE Global study will be higher than originally planned at the commencement of the study.

The FOXFIRE Global study aims to evaluate whether a first-line treatment strategy of using the current standard-of-care chemotherapy plus SIR-Spheres microspheres is more effective than chemotherapy alone, in patients with inoperable liver metastases from primary colorectal cancer.

The primary endpoint for the FOXFIRE Global study is overall survival. Overall survival is a measure of the effect of the treatment on the duration of survival (i.e. the time interval from randomisation until death).

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SARAH Study

As previously announced by the Company, the SARAH study is scheduled to complete recruitment during the fourth quarter of calendar year 2014 (Q4 C2014).

Due to the rapid recruitment of patients at participating French hospitals, the SARAH study is presently well ahead of schedule. However, an interim analysis undertaken by the principal investigator and study statistician has demonstrated a higher rate of treatment cross-over than assumed in the original design of the SARAH study. While this has necessitated the recruitment of an additional 60 patients onto the study, patient recruitment will still be completed during Q4 C2014 as scheduled.

The SARAH study is an independent investigator-initiated study sponsored by the Assistance Publique Hôpitaux de Paris (AP-HP) that aims to evaluate whether treatment with SIR-Spheres microspheres is more effective than the current standard-of-care drug sorafenib, in patients with inoperable hepatocellular carcinoma (HCC). The SARAH study is comparing SIR-Spheres microspheres and sorafenib head-to-head.

The primary endpoint for the SARAH study is overall survival. Overall survival is a measure of the effect of the treatment on the duration of survival (i.e. the time interval from randomisation until death).

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