

# AHCC Trials Group

Newsletter Volume 2, Issue 2 / NOV 2011

## Contents

### 1 The Buzz!

- AHCC06 Investigator Meeting (4 Sept 2011, HK)

### 2 Happenings

- AHCC02 Paper Published in British Journal of Cancer
- AHCC05 Results presented at Asian Pacific Hepato-Pancreato – Biliary Association Congress Melbourne 2011
- In the News!

### 3-6 Highlights – AHCC06

- Study Status
- Site Initiation Visits

### 6 Announcements

## AHCC Trials Group

**Group Chair:** Prof. Soo Khee Chee

**Protocol Chair:** Prof. Pierce Chow

**Trials Group Website:**

<http://www.scri.edu.sg/index.php/ahcc-trials-group>

**Contact Details of the Network**

**Secretariat:**

**Ms. Cecilia Yuan**

[cecilia.yuan@scri.edu.sg](mailto:cecilia.yuan@scri.edu.sg)

**DID:** (65)6508 8354

**Fax:** (65)6508 8317

**Ms. Chan Wai Ming**

[waiming.chan@scri.edu.sg](mailto:waiming.chan@scri.edu.sg)

**DID:** (65)6508 8314

**Fax:** (65)6508 8317

**Mailing Address:**

31 Biopolis Way, Nanos #02-01

Singapore 138669

**Trial Coordinating Centre:**

## The Buzz!

### AHCC06 Investigator Meeting (4 Sept 2011, Hong Kong)



The AHCC06 Trial held its first investigator meeting in Hong Kong at the Renaissance Harbourview Hotel on 4 September 2011, right after the closing ceremony of the ILCA conference. The much awaited event saw the active participation of over 30 investigators from Indonesia, Korea, Myanmar, Philippines, Singapore and Taiwan. The meeting posed an excellent opportunity for the participants to have an intensive discussion on the latest protocol amendments and challenges faced by each site. It drew valuable feedback from the floor and the different scenarios presented by the investigators shed new insights on the scientific and operational aspects of the trial. In addition, there were also technical inputs from Dr. Rheun-Chuan Lee who wrapped up the stimulating learning event with the sharing of his expertise on SIRT delivery. On the whole, it was a fruitful session and the study team would like to especially thank the investigators, the guest speakers – Prof. Pierce Chow, Prof. Khin Maung Win, Dr. Rheun-Chuan Lee and Sirtex for making this event a success.



*Prof. Pierce Chow presenting a token of appreciation to Prof. Khin Maung Win (top) and Dr. Rheun-Chuan Lee (bottom)*

SCIENTIFIC COLLABORATION FOR RESEARCH INNOVATION



## AHCC02 Paper Published in British Journal of Cancer!



*Br J Cancer. 2011 September 27; 105(7): 945–952.*

### AHCC02: Randomised Double-blind Trial of Megestrol Acetate vs Placebo in Treatment-naive Advanced Hepatocellular Carcinoma

was published in the British Journal of Cancer on 27 September 2011. The paper is accessible to the public online at the following link >>

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3185948/?tool=pubmed>.

Alternatively, the paper can be viewed at the AHCC Trials Group website.

### The Principal Investigators

#### AHCC02 Study:

Prof. Jin-Mo Yang, *Korea*  
Prof. Khin Maung Win, *Myanmar*  
Prof. Michael Findlay, *New Zealand*  
Dr. Rolley Rey Lobo, *Philippines*  
Prof. Soo Khee Chee, *Singapore*  
Prof. Pierce Chow, *Singapore*  
Prof. Hoang Hoa Hai, *Vietnam*  
Prof. Nguyen Ba Duc, *Vietnam*

#### AHCC05 Study:

Prof. Han Ho-Seong, *Korea*  
Dr. Harjit Singh, *Malaysia*  
Prof. Khin Maung Win, *Myanmar*  
Dr. Alexander Chung, *Singapore*  
Dr. Choo Su Pin, *Singapore*



### In The News!

#### *New cancer treatment gives new lease of life*

Though hugely shocked, Mr. Lee did not lose hope when he was diagnosed with stage 4 liver cancer almost 3 years ago.

Read the personal account by one of the longest surviving patient of AHCC05 trial on his experience and journey through the study.

The article can be viewed at the AHCC Trials Group website – Newsroom.

## AHCC05 Results presented at Asian Pacific Hepato-Pancreato-Biliary Association Congress, Melbourne 2011

### Phase I/II Study of SIR-Spheres plus Sorafenib (Chemo-Radiotherapy) as first line treatment in patients with non-resectable primary hepatocellular carcinoma

Following the previous presentation of AHCC05 trial at the ASCO meeting in Chicago last year, the promising results from AHCC05 were presented once again by Prof. Pierce Chow at the Asian Pacific HPBA 3rd Biennial Congress on 30 September 2011 in Melbourne.



**AHCC05  
Manuscript in  
progress!**

# Highlights

## AHCC06 (SIRveNIB)

Phase III Multi-Centre Open-Label Randomized Control Trial of Selective Internal Radiation Therapy (SIRT) Versus Sorafenib in Locally Advanced Hepatocellular Carcinoma

**Protocol Chair:**

Prof. Pierce Chow, Singapore General Hospital (Department of General Surgery)



Visit the AHCC06 Recruitment Website at: <http://www.sirvenib.com/>

### Study Status:

For the 2<sup>nd</sup> half of 2011, the trial saw a bumper crop of site initiations. 6 sites in Korea were initiated from 14-15<sup>th</sup> June 2011 and we also saw Penang Adventist Hospital, Malaysia; Queen Mary Hospital, Hong Kong and National Taiwan University Hospital, Taiwan being initiated on 17-18<sup>th</sup> August 2011, 5<sup>th</sup> and 30<sup>th</sup> October 2011 respectively. The latest sites included in the list of recruiting centers are St Luke’s Medical Center and Makati Medical Center on 14<sup>th</sup> and 15<sup>th</sup> November 2011.

As of today, 21 sites (5 Singapore, 16 overseas) have been initiated and are currently recruiting. A total of 91 patients have been enrolled into the trial with 45 patients randomized to the SIR-Spheres treatment and 46 patients to the Sorafenib treatment arm. We are looking forward to more sites being initiated in this final quarter of 2011!

### Site Initiation Visits!

#### Queen Mary Hospital



The AHCC06 study team together with site PI - Prof. Ronnie Poon (center) and his team.

**Jenny Zhang, CRA for QMH reports:**

“Since its establishment in 1937, Queen Mary Hospital has become one of the largest acute regional hospitals of Hong Kong and is also the flagship teaching hospital of the Faculty of Medicine, University of Hong Kong. On 5<sup>th</sup> October 2011, we went down to the site to conduct the SIV and train the study team on the operations and logistics of the trial. As of now, there is no patient randomized from QMH, however the site is doing active screening for the study and I believe we will have the 1st patient randomized by QMH in the near future!”

### Centers Open for Recruitment:

**Hong Kong:**

Queen Mary Hospital

**Indonesia:**

Cipto Mangunkusumo Hospital

**Korea:**

Asan Medical Center  
Korea University Anam Hospital

Seoul National University Bundang Hospital  
Seoul St. Mary’s Hospital  
Severance Hospital  
St. Vincent’s Hospital

**Malaysia:**

Penang Adventist Hospital

**Mongolia:**

National Cancer Center

**Myanmar:**

Yangon GI & Liver Centre

**New Zealand:**

Auckland City Hospital

**Philippines:**

Makati Medical Center  
St. Luke’s Medical Center  
The Medical City

**Singapore:**

Changi General Hospital  
Khoo Teck Puat Hospital  
National Cancer Centre  
National University Hospital  
Singapore General Hospital

**Taiwan:**

National Taiwan University Hospital





- Asan Medical Center
- Korea University Anam Hospital
- Seoul National University Bundang Hospital
- Seoul St. Mary's Hospital
- Severance Hospital
- St. Vincent's Hospital



Posing for a group photo: The investigators and representatives from the AHCC06 study team, Sirtex and ADM Korea.

**Jenny Zhang, CRA for QMH reports:**

“We conducted a centralized Site Initiation Visit meeting for 6 Korea sites participating in AHCC06 trial. The meeting was held in Ramada Seoul Hotel on 14<sup>th</sup> and 15<sup>th</sup> June, 2011. We were really grateful that many Korean investigators made great efforts to attend the meeting despite their extremely tight schedules. Our Korea partner ADM did a great job to coordinate with the sites and organize this meeting for us. The SIV went very well with investigators and site staff having active discussions during the meeting. As of now, the Korea centers have successfully randomized 5 patients. I’m very confident that Korea sites will make significant contributions to the recruitment of AHCC06 study.”

## Penang Adventist Hospital

**Pritha Bhadra, CRA for PAH reports:**

“Our SIV for Penang Adventist Hospital (PAH) for AHCC06 study was conducted on 17<sup>th</sup> and 18<sup>th</sup> August 2011.

Penang Adventist Hospital is a not-for-profit medical institution in Penang, Malaysia. It is part of an international network of more than 500 hospitals and healthcare facilities operated by the Seventh-day Adventist Church. PAH is also JCI accredited. Dr. Aloysius (site PI) and his team gave us a very warm welcome to the hospital. We visited the site facilities namely – the CT Scan department, X-ray department, Pharmacy and the Laboratory facilities. The new Laboratory which we saw during our visit incorporates some of the latest equipments for the tests.

Our SIV on the first day went very well – during which, Prof Pierce Chow presented the Protocol Overview to Dr. Aloysius and his team, and I presented the Operations Overview. The team had also organized a wonderful lunch for us. The second day of the SIV was mainly RDC training and other logistics training for the site staff. The team was very friendly and extremely co-operative throughout the visit. Overall, it was a wonderful experience. We’re looking forward to patient enrolment at the site which would give me another chance to visit the hospital and the team soon!”



Top: Pritha presenting on trial operations to Dr. Aloysius’s team. Bottom: Having a discussion with study coordinator, Ms Qym Ho (center)

## National Taiwan University Hospital



Top : Prof. Pierce Chow and Dr. Brian Goh (SGH) chairing the protocol discussion.

Bottom: Giving a token of appreciation to the site PI, Dr. Liang Po-Chin.

Since its inauguration in 1895, National Taiwan University Hospital (NTUH) has made noteworthy contributions to the development of medical care in Taiwan through its teaching, research, educational system, diagnostic and treatment techniques, or innovative research and development. As a leading medical center, NTUH is very committed to support biomedical/clinical research in her mission to transfer knowledge from bench to bedside and develop new therapeutics and applications that benefits patients. One of the main supporting infrastructures in research, NTUH's National Center of Excellence for Clinical Trial and Research is an established center that has supported NTUH in its investigator-initiated research projects. Its achievements have earned NTUH greater renown for its research capabilities and high standards of care.

The AHCC Trials Group had the opportunity to collaborate with NTUH on the AHCC06 trial. The journey to kick-start the trial in Taiwan was paved with many challenges, but the investigators remained positive and were very supportive of the trial. Overcoming all odds, NTUH was initiated on 30<sup>th</sup> October 2011 and is the first site in Taiwan to start recruitment. We anticipate more Taiwan sites being initiated by end of this year!

## St. Luke's Medical Center

St. Luke's Medical Center was established in 1903 by the American Missionaries as a charity ward and dispensary hospital. Today, St. Luke's is transformed into a world-class center of healthcare excellence whose expertise includes cardiovascular medicine, neurology and neurosurgery, cancer, ophthalmology, and digestive and liver diseases. In 2003, St. Luke's achieved one of its significant milestones by being the first hospital in Philippines to achieve Joint Commission International (JCI) accreditation.

In support of its mission to deliver high quality healthcare, St. Luke's dedicates much resources to medical/clinical research and continuing education. The Trials Group is excited to be in partnership with St. Luke's on the AHCC06 trial. On 14<sup>th</sup> Nov 2011, St. Luke's was initiated and is officially recruiting now.



Top: Presentation during site initiation.

Bottom: Prof. Pierce Chow and AHCC06 study team, together with site PI - Dr. Ian Cua (Center) and his team.



## Makati Medical Center

Makati Medical Center is a privately owned hospital that was founded by Dr. Constantino P. Manahan and other distinguished doctors in 1969. Since then, the hospital has become one of the top medical research and best equipped healthcare institutions in Asia. The medical center's record of achievements include performing the first successful heart transplant in the Philippines and also the opening of the country's first intensive care unit, first Cardiology training centre, and first Computer Imaging Institute at its premises.

The newly opened Liver Care Center is one of the latest additions to the state-of-the-art facilities available in the medical center, and it is headed by Dr. Catherine Teh, who is also our site PI for the AHCC06 trial. On 15<sup>th</sup> Nov 2011, the site was initiated and we look forward to the 1<sup>st</sup> patient recruited at the site!



Left to Right: Dr. Benjamin Benitez Jr. (Co-I), Dr. Ernesto Olympia (Co-I), Prof. Pierce Chow, Dr. Catherine Teh (Site PI)



## Announcements



Ms. Cecilia Yuan  
SCRI Project / Clinical Research  
Network Manager

We would like to welcome Cecilia to the AHCC Trials Group as part of the Secretariat. Cecilia has a Bachelors Degree in Applied Sciences from the University of Sheffield Hallam, UK and a Masters Degree in Management from the University College of Dublin, Ireland. She has 20 years of experience in the Pharmaceutical industry and CROs, holding various positions including Regulatory, CRA, Training, Business and Project Manager. Her expertise also includes organizing scientific symposiums and conferences across Asia Pacific, Africa, Middle East and Latin America. Prior to being an independent consultant, Cecilia was a Business Manager with Choice Pharma CRO.



From this month onwards, Cecilia will be taking over the secretariat role from Priscilla. We would also like to take this opportunity to thank Priscilla for her past contributions and support as the AHCC Trials Group Secretariat for the past 12 years. Her new role will be to support the Family Medicine Research Network. We wish them all the best in their new roles!



## Acknowledgements:

Millennium Foundation Singapore for supporting the secretariat. National Medical Research Council Singapore, SingHealth Foundation, Sirtex Medical and Bayer for supporting our clinical trials.