BioSpectrum the business of Bio & Health Sciences ASIA EDITION

Celsion launches cancer drug trial in China

08 March 2016 | News | By BioSpectrum Bureau

Celsion launches new cancer drug trial in China

Singapore: Celsion Corporation, a fully-integrated oncology company focused on the development of a portfolio of innovative cancer treatments, has launched OPTIMA Study in China.

The OPTIMA Study is the company's global pivotal, double-blind, placebo-controlled trial, evaluating ThermoDox, Celsion's proprietary heat-activated liposomal encapsulation of doxorubicin, in combination with radiofrequency ablation standardized to 45 minutes (sRFA) versus sRFA alone to treat newly diagnosed patients with (hepatocellular carcinoma) HCC.

Professor Ronnie T.P. Poon, medical director, Hong Kong Integrated Oncology Center, Honorary Professor of Surgery at the University of Hong Kong Queen Mary Hospital, and member of the International Liver Cancer Association (ILCA) Governing Board discussed strategies for treating different stages of primary liver cancer, also known as HCC; including intermediate stage HCC which has been previously thought to be incurable. New treatment strategies, most notably an optimized RFA procedure with the investigational drug, ThermoDox, show clear promise as a potential cure for intermediate HCC in the years ahead.

Michael H Tardugno, chairman, president and chief executive officer, Celsion said, "Our researchers and principal investigators recognize the importance of the OPTIMA Study to the medical community and its potential to significantly improve overall survival of newly diagnosed HCC patients. With approximately 50 percent of the 850,000 new cases of primary liver cancer diagnosed each year originating in China, China represents a significant market opportunity and key element of our global development strategy for ThermoDox."

The Phase III OPTIMA Study is expected to enroll up to 550 patients globally, and has been successfully enrolling patients at 50 clinical sites in 12 different countries in North America, Europe and Asia Pacific. In December 2015, the Company announced that it had received a Clinical Trial Application (CTA) approval from the China Food and Drug Administration (CFDA) to conduct the ongoing Phase III OPTIMA Study at up to 20 additional clinical sites in China. The Company aims to

enroll more than 200 patients in the China territory, the minimum number required by the CFDA to file a New Drug Application (NDA), assuming positive clinical results.

"With an extremely high incidence rate of HCC in China, the compelling survival data from the Chinese subgroup analysis in the HEAT Study underscores the importance of further exploring the potential that exists for ThermoDox in combination with sRFA to serve as a new curative treatment for primary liver cancer, a disease with limited treatment options," said Professor Min Hua Chen, Chief Expert, Department of Ultrasonography, School of Oncology, Peking University, Lead Investigator for the OPTIMA Study in China, and former HEAT Study Investigator. "It is a great honor to be involved with the OPTIMA Study, and I look forward to working with Celsion and my research colleagues as the study progresses."