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Celsion, Hisun Pharma enter tech development deal

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Singapore: Celsion, a leading oncology drug development company, and Zhejiang Hisun Pharmaceutical, a leading Chinese pharmaceutical company, have entered into a technology development agreement for ThermoDox for the greater China territory.

Under the terms of the agreement, Hisun will pay $5 million to Celsion immediately, while Celsion will provide Hisun with support for its ThermoDox manufacturing development program. This payment is non-refundable and comes in advance of Celsion's expected reporting of results from its pivotal phase III trial (the HEAT Study) in hepatocellular carcinoma (HCC), also known as primary liver cancer later this month.

In addition, the companies anticipate signing an agreement in which Celsion provides Hisun an exclusive option to license ThermoDox for the Greater China market, which includes China, Hong Kong and Macau. This option period will be secured by a second $5 million payment that must be received by Celsion from Hisun within 60 days after execution of the Technology Development Agreement. The key provisions of the anticipated license agreement have been negotiated and agreed to by the parties and provide a basis for a definitive contract. These provisions are:

- A credit of $10 million from the two payments ($5 million for the technology development agreement and $5 million for the exclusive option) toward a non-refundable upfront license payment of $25 million due to Celsion at signing of the definitive license agreement.

- An approximate 10 year total value to Celsion of well over several hundred million US dollars, which includes $55 million in upfront milestone and regulatory milestone payments within the next 18 months; $45 million in milestone payments for reaching certain sales targets; and escalating double-digit royalties on net sales of ThermoDox in the Greater China Territory.

- Hisun will serve as both the manufacturer and distributor of the ThermoDox drug product for the Greater China Territory, and also take responsibility for local regulatory activities including submitting approvals in China to the state

Food and Drug Administration.

"Pursuing this arrangement with Hisun allows us to evaluate the fastest path to the China market, potentially the largest opportunity in the world for ThermoDox. A long-term partnership will provide the greatest synergies with respect to sales, marketing, distribution, and manufacturing, which could ensure significant value to the ThermoDox asset," said Michael H. Tardugno , Celsion's president and chief executive officer. "In addition, this partnership provides Hisun and Celsion with immediate access to an accelerated pathway for sFDA review and approval of ThermoDox, a business strategy with exceptional potential to serve China's HCC population, and strong, uncompromised economics for both parties."

Mr Hua Bai, CEO and chairman of Hisun, stated, "We are extremely excited to pursue this arrangement with Celsion. Hisun is well positioned to provide ThermoDox - potentially one of the most important and innovative drugs to treat HCC to patients in China, the world's largest market. China is one of the countries with the highest HCC incidence and mortality and, up until now, there has not been any standard of care for treating HCC in China."

He said this joint effort will most likely facilitate the local manufacturing and commercial launch in China, thereby providing physicians with more options for better care and prolonging the survival of HCC patients. "We are also hopeful that this collaboration will enable Hisun to increase its focus on more innovative drugs. Given the fact that we are a leading Chinese pharmaceutical company with international standards of R&D and manufacturing technology, Hisun will seek to manufacture and supply the global markets, along with distribution exclusivity in Greater China. This venture will help spearhead Hisun's globalization in manufacturing and commercialization capabilities," says Mr Bai.

The HEAT Study is being conducted under a US Food and Drug Administration (FDA) Special Protocol Assessment, has received FDA Fast Track Designation, and has been designated as a Priority Trial for liver cancer by the National Institutes of Health. The European Medicines Agency (EMA) has confirmed the HEAT Study is acceptable as a basis for submission of a marketing authorization application.

ThermoDox has been granted orphan drug designation in both the US and Europe. In addition to meeting the US FDA and European EMA enrollment objectives, the HEAT Study has also enrolled a sufficient number of patients to support registration filings in China, South Korea and Taiwan, three of the largest potential markets for ThermoDox around the world.