

## China NMPA Approves SynCore Biotechnology to Conduct Phase III Human Clinical Trial for SB05PC (EndoTAG®-1), A First-Line Therapy for Pancreatic Cancer

Taipei, Taiwan, Jun 16, 2019. SynCore Biotechnology Co. (4192:TT) announces that the company has been approved by China National Medical Products Administration (NMPA) to commence the Phase III human clinical trial for its oncology asset SB05PC (EndoTAG®-1), a novel drug for the first-line treatment of pancreatic cancer.

According to World Health Organization (WHO), China holds the highest incidence and mortality of pancreatic cancer, being responsible for 116,300 occurrences and 110,400 deaths in 2018 respectively. The current standard of cares cannot significantly improve the overall survival rate, which leaves a great gap of unmet medical needs. Judging from the results of the completed Phase II study, SB05PC (EndoTAG®-1) shows great potential in prolonging overall survival when compared with Gemcitabine, the standard first-line therapy for pancreatic cancer in China. SB05PC (EndoTAG®-1) shall provide better treatment option and opportunity once been approved in China.

SynCore holds diverse and strategic plans for SB05PC (EndoTAG®-1) in different countries. In China, Gemcitabine in the major drug in treating pancreatic cancer, standing for 25% of chemo drug usage. The incidence and mortality rates are also higher in tier 1 cities include Beijing and Shanghai due to highly-struggled lifestyle and intensive pressure. Owing to these, SynCore combines SB05PC (EndoTAG®-1), a cationic liposomal paclitaxel, with gemcitabine in targeting locally advanced and/or metastatic pancreatic cancer for first-line treatment, in comparison with gemcitabine monotherapy. The completed Phase II study shows not only prolonged overall survival but also ameliorated adverse events, which renders higher life quality for pancreatic cancer patients. SynCore will also set study centers at high tier cities in order to accelerate subject enrollment.

Paclitaxel and gemcitabine are mature chemo options for various cancer types, both account for top 10 anticancer drugs in Chinese public healthcare systems. The annual revenue for these two blockbusters are RMB 5.7 billion and 2.5 billion, ranking as top 1 and top 9 sales in 2017 in Chinese public healthcare systems respectively. Serving as new formulation of paclitaxel, SB05PC (EndoTAG®-1) combines with gemcitabine to target first-line pancreatic cancer treatment, which is a promising new drug in China. SynCore is also actively seeking local partners for co-development and out-licensing for this project.





## **About SynCore Biotechnology**

SynCore Biotechnology Co., Ltd. (4192:TT) is a biopharmaceutical company with a comprehensive pipeline portfolio of new drugs in the areas of oncology, ophthalmology, dermatology and infectious diseases. The EndoTAG® technology platform is wholly owned by SynCore Bio. Please visit the Company's website at <a href="http://www.syncorebio.com/">http://www.syncorebio.com/</a>

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