

OncoTherapy Science, Inc.

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Announcement about the progress of phase III clinical trial (COMPETE-PC Study (COMBined PEptide ThErapy for Pancreatic Cancer)) of the peptide cocktail vaccine for patients with pancreatic cancer

OncoTherapy Science, Inc. (President & CEO: Takuya Tsunoda; hereinafter, "OncoTherapy") reports the current state of phase III clinical trial (COMPETE-PC Study (COMBined PEptide ThErapy for Pancreatic Cancer)) using the peptide cocktail vaccine "C01" (hereinafter "C01").

COMPETE-PC Study is a multicenter randomized double blind, placebo control, phase III clinical trial (confirmatory study) in the patient with pancreatic cancer which is refractory to the standard therapy, being solely conducted by OncoTherapy as a pivotal study.

Patient enrollment had been commenced since 25th May 2012 and the study is now being conducted at 47 medical departments in 43 institutions throughout Japan.

OncoTherapy announces here that the study is proceeding on schedule and the number of enrolled patients has reached over 200 as of the release date. OncoTherapy continues the enrollment of patients targeting the completion of planned 300 enrollments within this year, paying full attention to the safety.

Furthermore, the third interim analysis (object: to assess the clinical efficacy of C01) by the Independent Data-Monitoring Committee is planned to be done according to the protocol. The final data analysis is planned 365 days after the enrollment of the last patient according to the protocol. Provided the result of this analysis meets the predefined criteria in the study plan, OncoTherapy is going to submit a New Drug Application for C01 to Japanese regulatory authority, Pharmaceutical and Medical Devices Agency (PMDA).

OncoTherapy has decided to leave fiscal 2013 full-year forecasts announced on 15th May, 2013 unchanged.

C01 is the cocktail vaccine product which contains multiple peptide vaccines targeting

the tumor-specific antigen identified by genome-wide expression profile analysis and the endothelial cells of tumor neovessels, and is expected to suppress the growth and progression of pancreatic cancer through giving the damage to both pancreatic cancer cells and tumor neovessels.