

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 patients with pancreatic cancer which are refractory to the standard therapy, being solely conducted by OncoTherapy as a pivotal study.

OncoTherapy announces here that the Independent Data-Monitoring Committee has recommended that COMPETE-PC Study should be stopped because of the low probability of significant elongation of overall survival period in C01 group compared to the placebo group, which is the primary endpoint predefined in the clinical protocol, at the third interim analysis (object: to assess the clinical efficacy of C01).

Upon receiving this recommendation, OTS has decided to stop the study earlier.

Clinical development of C01 in other indications is currently underway. In addition to the on-going investigator initiated clinical trials such as evaluation of preventive activity of C01 for the recurrence of pancreatic cancer after surgical resection and efficacy of C01 in combination with the primary therapy, clinical trials for other cancer types including biliary tract cancer are also planned. Since the Phase II clinical trial using the Elpamotide, one of the active components of C01 targeting tumor neovessels, suggested the efficacy in biliary tract cancer, C01 is strongly expected to have more potency in this cancer type by synergistic targeting both tumor neovessels and tumor -specific antigen. OTS is planning to start this clinical trial as soon as possible.

This stopping of clinical trial has no effect on the other pipelines which are in preparation or underway. OncoTherapy will inform about the effect on the fiscal 2013 full-year forecasts announced on 15<sup>th</sup> May, 2013 when more details become available.