OncoTherapy Science, Inc.
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Announcement of the presentation of the final results for Phase II Clinical trial in patients with biliary tract cancer at the European Cancer Congress 2013.

OncoTherapy Science, Inc. (President & CEO: Takuya Tsunoda; hereinafter, "OncoTherapy") announces that the final results from Phase II clinical trial in patients with biliary tract cancer at the European Cancer Congress 2013, on 30th September 2013 (Local time).

This clinical trial had been conducted in patients with unresectable advanced and recurrent biliary tract cancer using ant-angiogenesis agent OTS102 (INN: Elpamotide) in combination with anticancer agents, at 14 institutions throughout Japan from July 2009 to October 2012.
Elpamotide is the investigational cancer vaccine product targeting the endothelial cells of tumor neovessels, under development by OncoTherapy.

[Summary of the presentation]
For the chemotherapy of advanced biliary cancer, Gemcitabine is generally used. In order to improve the clinical effect, we focused attention on the tumor angiogenesis which plays an important role in the proliferation of biliary tract cancer cells, and conducted Phase2 clinical trial using the epitope peptide derived from Vascular Endothelial Growth Factor Recepter-2 (VEGFR-2), one of the molecules involved in the tumor neovascularity.

This clinical trial was conducted in 54 patients with unresectable advanced or recurrent biliary tract cancer to evaluate the safety and efficacy of Elpamotide in combination with gemcitabine.

Overall survival (OS) of the patients treated with Elpamotide in combination with gemcitabine, which is the primary endpoint, was 10.05 months and suggested to prolong the OS when compared to that of the patients treated with gemcitabine alone (7.6 months, historical data from the PhaseII clinical trial).
Moreover, 1-year survival rate of the patients treated with Elpamotide in combination with gemcitabine was 44.4% and higher than that of the patients treated with gemcitabine alone (25.0%, historical data), suggested the improvement .

Taken these results suggesting the efficacy, further development of thie product is under consideration.