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Dear all,

Company Name : Delta-Fly Pharma, Inc.  
(Code number : 4598 TSE Growth Market)  
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Announcement for a phase 2/3 study of DFP-17729 to be started

Announcement for PMDA approval to do a phase 2/3 study of DFP-17729 combined with TS-1 versus TS-1 alone in patients with 3<sup>rd</sup> line to last line of pancreatic cancer.

This phase 2/3 study shall be done at 15 clinical sites in Japan. The primary endpoint of this study is overall survival (OS). When the therapeutic effect of DFP-17729 with TS-1 is confirmed to be superior to TS-1 alone, DFP-17729 is expected to be NDA approval by PMDA and to be welcomed for cancer patients from viewpoint of safety and low medication cost having mechanism of tumor micro-environment (TME) regulator.

No effect on performance.

\*TS-1 is an anti-cancer drug developed in Japan by Taiho Pharmaceutical Co., Ltd. and approved in 1999. TS-1 belongs to a group of anti-cancer drugs called metabolic antagonists, and is an improved version of 5-FU, which also belongs to the metabolic antagonist group. It is mainly used to treat the following cancers: gastric cancer, colorectal cancer (colon cancer), head and neck cancer, non-small cell lung cancer, breast cancer, pancreatic cancer, and biliary tract cancer.

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