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Dear ALL

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Completion of Patient Enrollment for the Phase 2 Portion of DFP-17729
Phase 2/3 Randomized Study for Pancreatic Cancer in Japan

Delta-Fly Pharma is pleased to announce that it has received notification from participating clinical sites in Japan that the patient enrollment has been completed in the phase 2 portion of DFP-17729 phase 2/3 double-blind, randomized, placebo-controlled study in combination with TS-1 in patients with unresectable, recurrent, or advanced pancreatic cancer.

The study employs an "adaptive seamless Phase 2/3 design" to efficiently verify the endpoint of overall survival (OS), and the number of patients in the Phase 3 portion will be increased or decreased depending on the superiority in OS in the Phase 2 portion, allowing for a rapid transition to the Phase 3 portion.

If good results in OS are confirmed in this study, the additional benefit of DFP-17729 will be demonstrated, making it possible to provide a patient-friendly cancer micro-environment improving agent that is oral medication, high safety, and cost-effectiveness.

About DFP-17729

DFP-17729 is an orally alkalizing agent made from sodium citrate and potassium citrate which inhibit tumor growth effectively without serious toxicity through neutralization of acidic tumor micro-environment (TME).

Nippon Chemiphar supplies DFP-17729 drug product and placebo to this randomized study.

About TS-1

TS-1, also known as S-1, is an oral anti-cancer drug containing a combination of three active pharmaceutical ingredients: tegafur, gimeracil, and oteracil potassium. It is classified as a fluoropyrimidine-based antimetabolite agent. In essence, it is designed to enhance the effectiveness of the chemotherapy drug 5-fluorouracil (5-FU) while mitigating its side effects.