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Dear ALL

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First Patient Enrolled in Phase 2/3 Randomized Study of DFP-17729
for Pancreatic Cancer in Japan

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

The Phase 2 portion of this Phase 2/3 study will be conducted at 15 clinical sites in Japan. The endpoint is overall survival (OS). If superiority is demonstrated in this trial, the additional benefit of DFP-17729 will be demonstrated, making it possible to provide a patient-friendly cancer treatment drug that is oral, highly safe, and cost-effective.

About DFP-17729

DFP-17729 is an orally alkalizing agent made from 1:1 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.