

August 31, 2026

Dear ALL

Company Name : Delta-Fly Pharma, Inc.
(Code number : 4598 TSE Growth Market)
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Update on the Phase 2/3 Clinical Trial of DFP-17729

Phase 2 data analysis scheduled for January 2027

Current median OS is approximately 7.2 months among 78 enrolled patients

Delta-Fly Pharma Co., Ltd. is pleased to provide an update on the ongoing Phase 2/3 clinical trial of DFP-17729, a cancer microenvironment modulator, being conducted in Japan in patients with unresectable, recurrent, or advanced pancreatic cancer receiving third-line or later treatment.

As announced on May 28, patient enrollment in the Phase 2 portion of the study has been completed.

Follow-up of all patients is expected to be completed by the end of November 2026, approximately six months after enrollment and randomization of the last patient. The overall survival (OS) database is scheduled to be locked in December 2026. An interim analysis and an independent review by the Data Safety Monitoring Board (DSMB) are planned for January 2027. Based on the results of these assessments, a decision will be made regarding whether to proceed to the Phase 3 portion of the study and the required sample size for Phase 3.

If the study proceeds to Phase 3, patient enrollment is planned to resume in March 2027 following revision of the study protocol and approval by the Institutional Review Board (IRB) at each participating site. The randomized, double-blind controlled study design will be maintained.

Current Follow-up Status

Among the 78 patients enrolled in the Phase 2 portion, no safety issues affecting continuation of the study have been identified to date. Under ongoing blinded conditions, the current survival rate is 71.8%, with median overall survival (OS) of approximately 7.2 months.

Patients with advanced pancreatic cancer receiving third-line or later treatment generally have a poor prognosis, with median OS reported to be approximately three to four months. Although the study remains ongoing under blinded conditions and the final efficacy analysis has not yet been completed, the currently available data suggest the potential of DFP-17729 to contribute to prolonged survival.

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