

February 25, 2026

Dear All,

Company Name: Delta-Fly Pharma, Inc.

(Code number : 4598 TSE Growth Market)

Inquiries: Kenzo Iizuka, Senior Vice President, R&D

(Contact: <https://www.delta-flypharma.co.jp/en/contactentrance/>)

### **Follow up Interim analysis for Phase 3 Study of DFP-10917**

The Data Safety Monitoring Board (DSMB) has made a Go/No-Go decision regarding Phase 3 clinical trial of DFP-10917 monotherapy based on the interim analysis data in patients with acute myeloid leukemia in the third or subsequent line of treatment (R/R AML) in the United States. The study was discontinued due to the failure to demonstrate superiority as outlined in the protocol\*<sup>1</sup>. We have since obtained and carefully reviewed the interim analysis data, and we are pleased to provide a summary of the results.

- ① While there was no significant difference in response rate (CR + CRi + CRp + PR), the DFP-10917 group demonstrated a higher response rate than the control group.
- ② There was no significant difference in overall survival (OS) between the DFP-10917 group and the control group\*<sup>2</sup>. However, the DFP-10917 group had a longer survival period than the control group treated with intensive chemotherapy.
- ③ DFP-10917 demonstrated excellent efficacy in a subset of AML patients with poor prognosis who are largely resistant to conventional therapies.

The U.S. Food and Drug Administration (FDA) has granted orphan drug designation to DFP-10917. Furthermore, as DFP-10917 is an inexpensive small-molecule compound, if approved through a New Drug Application (NDA), it could provide therapeutic and economic benefits to patients with R/R AML. Therefore, we plan to enter into discussions with the FDA regarding conditional NDA approval.

\*1 The clinical trial protocol is a study to compare and verify the complete remission rate (CR) and overall survival (OS) of the investigational drug group, DFP-10917 alone, with the control group, which consists of intensive chemotherapy or non-intensive chemotherapy.

\*2 The control group, non-intensive chemotherapy, includes patients receiving combination therapy with Venetoclax.

END