

April 16, 2026

Dear All,

Company Name: Delta-Fly Pharma, Inc.  
(Code number : 4598 TSE Growth Market)  
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**Notice Regarding Preparations for Discussions with the U.S. FDA on  
DFP-10917 Monotherapy and Combination Therapy with Venetoclax**

We hereby announce the progress of the development of DFP-10917 as follows:

1. DFP-10917 Monotherapy (Phase 3 Study)

In the interim analysis of a Phase 3 trial of DFP-10917 monotherapy conducted at multiple centers in the United States targeting patients with relapsed/refractory acute myeloid leukemia (R/R AML, 3rd- and 4th-line treatment), although no statistically significant difference was observed in the primary endpoint compared to the control group, the following positive results were obtained:

- The overall response rate (ORR) exceeded that of the control group
- A longer overall survival (OS) was observed compared to the intensive therapy subgroup within the control group (stratified analysis)
- Efficacy was suggested in patient populations with poor-prognosis genetic mutations, including TP53

Based on these results, the Company is proceeding with preparations for discussions with the FDA toward a New Drug Application (NDA) for conditional approval of DFP-10917 monotherapy, with support from external experts experienced in FDA regulatory matters.

2. Combination Therapy of DFP-10917 with Venetoclax (VEN)

In a Phase 1/2 study evaluating DFP-10917 in combination with Venetoclax (VEN) in patients with relapsed/refractory AML (2nd-line treatment and beyond), the following promising results were obtained:

- Phase 1 portion: ORR 50% (CR: 1 patient, MLFS: 2 patients)
- Phase 2 portion: ORR 53% (CRi: 3 patients, MLFS: 3 patients, PR: 3 patients)
- 4 patients transitioned to hematopoietic stem cell transplantation (SCT)

Furthermore, three of these patients are still receiving treatment, one patient with CRi converted to CR, and long-term survival is being observed in other cases including MLFS and PR patients.

Based on these results, the Company is preparing for discussions with the FDA for an End-of-Phase 2 meeting toward a Phase 3 trial of the combination therapy.

### 3. Future Strategy and Partnerships

The Company has entered into confidentiality agreements with major overseas pharmaceutical companies that have shown interest in the Phase 3 interim results of DFP-10917 monotherapy and the VEN combination study, and has provided them with detailed information.

If discussions with these companies progress, there is potential for co-development and joint promotion of the NDA for conditional approval of DFP-10917 monotherapy, and a global Phase 3 trial for the VEN combination therapy.

The Company will continue to actively promote development and partnership activities to maximize the value of DFP-10917.

END