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Dear All,

Company Name: Delta-Fly Pharma, Inc.
(Code number : 4598 TSE Growth Market)
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Announcement Regarding the International Trademark Registration and the Prospect of NDA Approval for DFP-10917

We hereby announce that trademark registration certificates for "RADBALGO" and "RADGAZEN," which are required in connection with the NDA (New Drug Application) approval of DFP-10917 (Radgocitabine), have been issued and internationally registered, including in China.

"RADBALGO" (International Registration No. 1600230) and "RADGAZEN" (International Registration No. 1600256) required the issuance of trademark registration certificates in China in order to complete registration under the Madrid Protocol designation. Accordingly, applications had been filed with the China National Intellectual Property Administration (CNIPA). As a result of these registrations, the products may now be marketed globally under the same brand names.

In addition, in response to requests from major global pharmaceutical companies interested in licensing the manufacturing and commercialization rights for DFP-10917 for the treatment of Relapsed/Refractory Acute Myeloid Leukemia (R/R AML), the Company is preparing for discussions with the U.S. Food and Drug Administration (FDA) regarding the potential conditional NDA approval of DFP-10917 monotherapy.

Furthermore, based on favorable results from the Phase 1/2 clinical study evaluating DFP-10917 in combination with Venetoclax, we plan to hold an End-of-Phase 2 Meeting with the FDA regarding the potential initiation of a Phase 3 clinical trial in second-line AML patients.

The major discussion points with the FDA regarding the potential conditional NDA approval are expected to include the following:

① DFP-10917 demonstrated efficacy compared with Intensive Therapy in a U.S. Phase 3 clinical study involving patients with R/R AML.
② DFP-10917 demonstrated efficacy in R/R AML patients harboring TP53 gene mutations, for whom currently available therapies have shown limited effectiveness.
③ In the Phase 1/2 clinical study, the combination therapy of DFP-10917 and Venetoclax demonstrated clinical benefit in AML patients who became relapsed/refractory following prior non-intensive therapy.
④ Under low-dose, long-term administration conditions, both DFP-10917 (a G2/M cell-cycle arrest agent) and Venetoclax (a Bcl-2 inhibitor) promoted apoptotic cancer cell death, and synergistic effects were observed.
⑤ DFP-10917 is a small-molecule compound and may contribute to reducing manufacturing costs and the financial burden on patients compared with antibody-based therapies.

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