

August 6, 2025

Dear All,

Company Name : Delta-Fly Pharma, Inc.
(Code number : 4598 TSE Growth Market)
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Progress status for Phase 1/2 study of DFP-10917 with Venetoclax (VEN)
in the 2nd line AML

We informed drug safety in the phase 1 portion of phase 1/2 study of DFP-10917 with Venetoclax (VEN) in the patients with 2nd line AML was confirmed on February 28th in 2025.

The phase 2 portion of this combo-study has been carried out by Simon's 2 steps statistical design, in which configured for picking useful new drug up effectively for the next phase 3 study.

In the 1st step, well completed 10 patients' enrollment and observed reasonable efficacy. Accordingly, DMC (Data Management Committee) agreed to move forward to the 2nd stage of this combo-study, in which 7 patients shall be enrolled after this. DMC will judge for entering in to phase 3 study followed by agreement by the FDA in US.

In the 2nd line AML therapy after VEN treatment, incomplete remission (CRi) or medical longitudinal facilitate (MLFS) was often observed, probably because of myelotoxicity induced by VEN.

For the above reason, DMC recommended to take the 2nd step in the phase 2 portion of this comb-study by dosing down VEN from 2 weeks to 10 days in the 1st cycle.

No effect on business operations.

END