

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 Morphologic Leukemia-free State (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