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Dear All,

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(Code number : 4598 TSE Growth Market)
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Announcement Regarding the Data Monitoring Committee Decision on the Phase 1/2 Study of DFP-10917 combination with Venetoclax in Relapsed or Refractory AML

We are pleased to announcement the results of the Data monitoring Committee (DMC) assessment for the Phase 1/2 study of DFP-10917 combination with Venetoclax (VEN) in the 2nd line relapsed or refractory acute myeloid leukemia (AML) conducted at four US Cancer Centers※.

As no dose-limiting toxicity (DLT) was observed among enrolled 6 patients in the Phase 1 cohort, seventeen patients were enrolled and assessed safety and efficacy in the Phase 2 dose expansion cohort by using Simon's two-stage min-max design. The DMC agreed that the changed regimen and dose level (DFP-10917 (4mg/m^2/day CIV) x 14 days + Venetoclax (400 mg/day) x 10 days) is safe and tolerable and recommended this regimen and dose for future studies.

The DMC reviewed the summary of reported responses and noted the overall response rate, 50% (1 patient of CR and 2 patients of MLFS) in the Phase 1 safety cohort, and 53% (3 patients of CRi and 3 patients of MLFS) in the Phase 2 expansion cohort. Accordingly, 4 patients transitioned to stem cell transplantation.

Although the original study design requiring over 9 responses among 17 patients to test a 53 % overall response rate which almost patients receive VEN as first-line and/or second-line prior treatment, the DMC agreed this response level experienced among the study patients, who do not have targeted or other treatment options, was sufficient to recommend future trials.

※ University of Virginia Hospital, University of California, Irvine Hospital, University of Vermont Hospital, and Wake Forest University Hospital.

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