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Dear All,

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（Code number : 4598 TSE Growth Market）
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Progress status of DFP-10917 involved clinical studies

We wish to provide an update regarding the progress of our DFP-10917-related pipeline, which is currently advancing through clinical trials this year.

The interim analysis of the Phase 3 comparative clinical trial of DFP-10917 monotherapy in patients with end-stage acute myeloid leukemia (AML) being conducted in the United States has required time for data cleaning. Nevertheless, clinical data related to efficacy assessment conducted at the institutions participating in the trial and enrolling patients, as well as central bone marrow analysis results conducted at MD Anderson Cancer Center, are now available. Once all clinical data entry and interim analysis are complete, we plan to submit the data to the Data Safety Management Board (DSMB) for an evaluation of clinical efficacy.

In addition, the Phase 2 portion of the Phase 1/2 clinical trial for DFP-10917 in combination with venetoclax (VEN) in patients with AML who have received one prior treatment with VEN is progressing using Simon's two-stage design, and we expect to complete the target patient enrollment in the second stage. After a certain period of patient follow-up necessary to assess efficacy, a Data Monitoring Committee (DMC) will assess efficacy and safety, followed by an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA).

For the next stage, if possible, we plan to collaborate with major global pharmaceutical companies that show interest and conduct Phase 3 comparative clinical trials globally.

In the United States, we have been conducting an expanded Phase 1 clinical trial (equivalent to an early Phase 2 clinical trial) of DFP-14927 as a drug delivery system (DDS) for DFP-10917 in patients with end-stage colorectal cancer. Although an improvement in the disease control rate (DCR) was observed, no tumor shrinkage such as complete response (CR) or partial response (PR) was observed. Therefore, we plan to continue the expansion cohort in patients with end-stage pancreatic cancer, one of cancer in which the

anti-cancer active substance DFP-10917 is easily released from the DDS DFP-14927 in cancer tissue.

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