

CPX-351 improves survival following allogeneic hematopoietic cell transplant in acute myeloid leukemia patients

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Acute myeloid leukemia, or AML, is a type of cancer of the blood and bone marrow. It occurs most often in older populations and progresses rapidly, interfering with the production of red blood cells, white blood cells and platelets. Treatments include chemotherapy, drug therapy and stem-cell transplants.

A <u>subgroup analysis</u> of a phase 3 trial shows that <u>older patients</u> with highrisk or secondary AML, who received initial treatment with CPX-351, had improved survival following allogeneic hematopoietic cell transplant, when compared with patients who received standard 7+3 cytarabine and daunorubicin as initial therapy. Moffitt Cancer Center physician Jeffrey Lancet, M.D., will present the results at the American Society of Hematology Conference Annual Meeting in San Diego.

Cytarabine combined with daunorubicin (7+3) is commonly used to treat AML; however, older patients with AML usually respond poorly to this treatment regimen alone. Patients who are eligible and respond to initial treatment often have the option to receive allogeneic hematopoietic cell transplants.

CPX-351 is a liposomal formulation of cytarabine and daunorubicin in a 5:1 molar ratio. This fixed molar ratio was found to be synergistic in preclinical studies, and subsequent phase 1 and phase 2 clinical trials demonstrated efficacy, with a particularly strong signal in patients with



secondary AML.

Previously reported results from a phase 3 trial revealed improved survival in patients with secondary or high-risk AML treated with CPX-351 compared with 7+3. An exploratory subgroup analysis of the phase 3 study was conducted to compare the outcomes of AML patients treated with CPX-351 or 7+3 who went on to receive allogeneic hematopoietic cell transplant. Out of 309 patients who took part in the trial, 52 patients in the CPX-351 treatment arm and 39 patients in the 7+3 arm received allogeneic hematopoietic cell transplants.

The first 100 days after allogeneic hematopoietic cell transplants represent a critical time. Patients treated with CPX-351 had a lower 100-day mortality rate than patients in the 7+3 group (9.6 percent versus 20.5 percent, respectively). Patients in the CPX-351 group also had a significantly better overall survival than patients in the 7+3 group. The median overall survival was not yet reached in the CPX-351 arm and was 10.25 months in the 7+3 arm.

Lancet, chair of Moffitt's Department of Malignant Hematology, will present the <u>study results</u> Monday Dec. 5 at 4 p.m. in San Diego Ballroom AB at the Marriott Marquis San Diego Marina.

Provided by H. Lee Moffitt Cancer Center & Research Institute

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