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Study shows improved response rates in myelodysplastic syndromes patients treated with lenalidomide and epoetin alpha

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Patients with myelodysplastic syndromes (MDS) suffer from a reduction in the number of different types of blood cells, including red blood cells leading to the development of anemia. Many patients with lower-risk MDS benefit from treatment with recombinant-erythropoietin (rHuEPO), which stimulates blood cell production. However, patients who become refractory to rHuEPO have few effective treatment options.

Alan F. List, M.D., president and CEO of Moffitt Cancer Center, will present interim results from the phase 3 ECOG-ACRIN E2905 Intergroup Study at the American Society of Hematology Annual Meeting in San Diego. The study shows that lenalidomide in combination with epoetin alpha produced better outcomes and similar toxicity as lenalidomide alone in patients with erythropoietin-refractory, lower-risk myelodysplastic syndromes (MDS).

Early phase clinical trials have demonstrated that lenalidomide improves blood cell production in transfusion-dependent non-del(5q) MDS, leading to transfusion-dependence in 26 percent of patients. Additionally, data from a pilot trial suggested that lenalidomide in combination with epoetin alpha may overcome resistance and improve response rates in erythropoietin-refractory MDS patients.

This observation led to the initiation of a phase 3 trial to assess if

lenalidomide combined with epoetin alpha improves the major erythroid response rate after 4 cycles of treatment when compared to lenalidomide alone in patients with low or intermediate-1 risk MDS who were unresponsive to rHuEPO treatment or were transfusion-dependent with serum erythropoietin levels greater than 500 mU/mL.

An interim analysis of 163 patients randomized to lenalidomide (n = 81) or lenalidomide + epoetin alpha (n = 82) showed that the study met the predefined stopping criteria. Lenalidomide + epoetin alpha treatment resulted in significantly better erythroid responses than lenalidomide alone among 116 evaluable patients, with a major erythroid response rate at 16 weeks of 33.3 percent for lenalidomide + epoetin alpha and 14.3 percent for lenalidomide alone. The treatment groups had similar rates and types of grade 3 or higher non-hematologic adverse events. Additionally, a biomarker analysis of responding patients suggested that the erythroid CD45 isoform may predict response to combination treatment.

List will present the study results Saturday, Dec. 3 at 4 p.m. in Grand Hall C of the Manchester Grand Hyatt San Diego.

Provided by H. Lee Moffitt Cancer Center & Research Institute