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Combining targeted drug with chemotherapy offers longer life to b-cell cancer patients

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Because of the significant benefit found in combining the targeted drug ibrutinib with standard chemotherapy for relapsed chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), an interim analysis has closed the international HELIOS phase III clinical trial.

Led by Mayo Clinic, researchers found that ibrutinib and chemotherapy (bendamustine and rituximab, known as BR) reduced the risk of death or cancer progression by almost 80 percent in patients with previously treated CLL or SLL, compared to use of BR alone.

The announcement was made at a press briefing at the 2015 meeting of the American Society of Clinical Oncology by HELIOS' senior investigator Asher Chanan-Khan, M.D., professor of medicine and chair of Hematology & Oncology, Mayo Clinic Cancer Center in Jacksonville, Florida.

"This finding represents a significant advancement in the management and treatment of this leukemia," says Dr. Chanan-Khan. "Although CLL remains incurable, this new regimen offers longer disease control and a decreased risk of relapse for our patients."

The HELIOS study—which enrolled 578 patients from centers around the world—was the first to compare, head-to-head, chemo immunotherapy alone to chemo immunotherapy plus a targeted drug in patients with CLL.

CLL, the most common adult leukemia in the U.S., is a B-cell cancer that is present in blood and lymph nodes. SLL is a B-cell cancer found only in lymph nodes.

Ibrutinib is an oral pill that blocks Bruton's tyrosine kinase (BTR), making the cancer vulnerable to death. "This BTR inhibitor interrupts the cellular signaling path that drives B-cell growth and survival," says Dr. Chanan-Khan.

Ibrutinib was approved by the U.S. Food and Drug Administration (FDA) for use in November 2013 for the treatment of mantle cell lymphoma, a subset of B-cell lymphoma. It was also approved in February 2014 for use in CLL, following a study of the agent alone in patients with very advanced disease who had been through multiple treatments.

The HELIOS trial was designed to test the two therapies in less heavily treated patients whose cancer had returned.

In the randomized study, 289 patients received ibrutinib plus BR, and the other 289 were treated with BR plus a placebo pill. At a median follow-up of 17.2 months, progression- free survival was significantly longer in the group who received the ibrutinib combination compared to those who did not.

Overall response rate in the BR/ibrutinib group was 83 percent versus 68 percent in the group treated with BR alone. At the time of analysis (18 months) 79 percent of the patients receiving ibrutinib remained in remission vs. only 24 percent who did not. Additional findings will be presented at the ASCO press briefing.

"We cannot say the very positive findings from this study were surprising, because we saw how effective ibrutinib can be when used

alone in advanced patients," says Dr. Chanan-Khan. "But we are pleased to see the great value ibrutinib offers even in the setting of chemotherapy. We are gratified to have multiple options for our patients."

More information: www.ncbi.nlm.nih.gov/pubmed/24901734

Provided by Mayo Clinic