Trial demonstrates one-year progression-free survival in 94% of patients with stage 3 or 4 classic Hodgkin lymphoma

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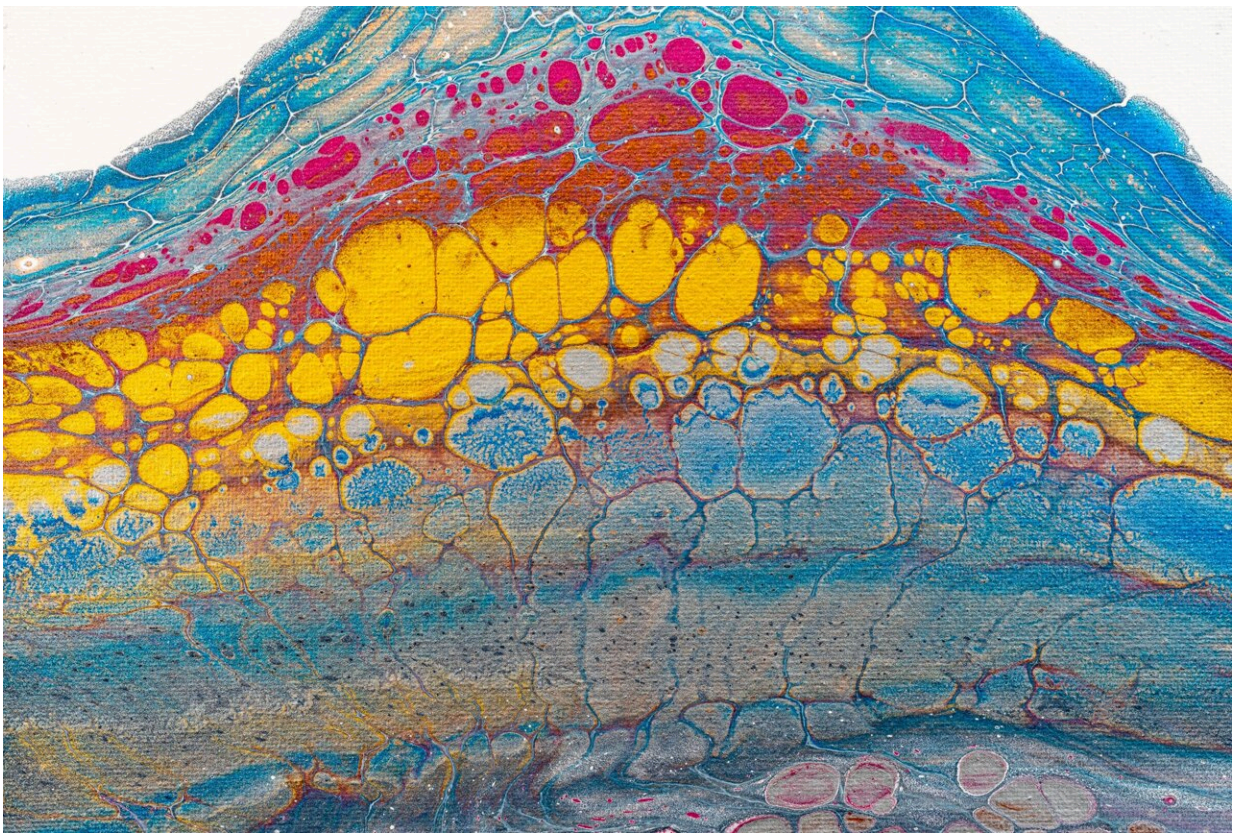

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A Phase 3 trial has demonstrated that patients with advanced stage (3 or 4) classic Hodgkin lymphoma who underwent initial treatment with

nivolumab, a PD-1 checkpoint inhibitor, and AVD chemotherapy (N-AVD) had a significantly lower risk of their cancer getting worse than patients treated with brentuximab vedotin, a monoclonal antibody, and AVD (BV-AVD) a year after starting treatment.

Ninety-four percent of adolescent and adult patients in the N-AVD group had progression-free survival compared with 86% in the BV-AVD arm. N-AVD was also well-tolerated as there were few serious immune-related side effects in the S1826 trial. The median follow-up was 12.1 months.

These late-breaking findings will be presented by City of Hope's Alex Herrera, M.D., at ASCO's 2023 Plenary Session, June 4, at 2:53 p.m. CT in Hall B1 and will be featured in the official ASCO press program.

Lead investigator on the study, Herrera is chief of the Division of Lymphoma at City of Hope, one of the largest cancer research and treatment organizations in the United States, and is an investigator with the SWOG Cancer Research Network.

"The results are remarkable. The combination of nivolumab and chemotherapy is potent and safe in patients with Stage 3 or 4 classic Hodgkin lymphoma as an initial treatment," said Herrera, "The therapy is poised to be a standard for treatment of advanced Hodgkin lymphoma. This is indeed great news for patients with this cancer as there is another effective and safe treatment option for them."

Georgie Garabet, 43, of Glendora, California, was one of the patients who participated in the trial. When Garabet began to feel sick in early 2020, he was a 40-year-old father of two children under the age of 3. His symptoms included uncontrollable itching all over his body and severe weight loss. After a few trips to emergency rooms and to his primary care doctor, he was eventually diagnosed with Stage 3 Hodgkin

lymphoma.

"I panicked when I heard the word cancer," Garabet said. At the same time, he was relieved to know what was causing his symptoms.

Garabet met Herrera and instantly felt he was in good hands. "He explained everything so well," he added. Garabet enrolled in the trial. After his first infusion, he felt exhausted but that was the worst he felt during treatment. After only four infusions, he was in remission. He was advised to continue the treatment in case any cancer lingered, and he did. "Now when people tell me they have cancer, I tell them not to panic. There are a lot of cures now," he added.

The S1826 trial, supported by the NCI and led by SWOG, is the largest classic Hodgkin lymphoma study ever conducted in the NCI's National Clinical Trials Network and is also representative of a diverse patient population. About a quarter of the enrolled patients were Black or Hispanic. A partnership with the Children's Oncology Group (COG) helped ensure the trial included young adolescents, and a quarter of enrolled patients were younger than 18 years old. Nearly two-thirds of all patients had Stage 4 cancer.

"This study speaks to the power of the National Clinical Trials Network and is an excellent example of the transformative work that the NCI funds," said Jonathan Friedberg, M.S., M.M.Sc., senior author of the study, chair of the SWOG Cancer Research Network's lymphoma committee and director of the Wilmot Cancer Institute at the University of Rochester.

"Hodgkin lymphoma is not a common disease and the NCTN enabled a large network of more than 200 pediatric and adult community providers and academic medical centers to work together. Because of that, we were able to get data very quickly and directly impact patient care. This

was a critical investment in cancer research and treatment."

Patients with Stage 3 or 4 classic Hodgkin lymphoma who had not been previously treated and were age 12 or older were eligible for the trial. Of a total of 976 eligible patients, 489 were enrolled in the N-AVD arm (nivolumab plus Adriamycin, vinblastine and dacarbazine), while 487 were part of the BV-AVD group. Each group received six infusion cycles of each combination therapy.

As expected with combination chemotherapy, the most common side effects included gastrointestinal and hematologic toxicities, and fatigue. However, less than 1% of patients needed radiation after trial treatment, which is a dramatic reduction in the proportion of patients being initially treated for Hodgkin lymphoma who need radiation, especially among pediatric patients.

"The ability to maintain high rates of relapse-free survival with minimal use of radiation therapy in children with newly diagnosed advanced stage Hodgkin lymphoma will be a paradigm shift," said Sharon Castellino, M.D., M.Sc., chair of the COG Hodgkin lymphoma committee and director of the Leukemia and Lymphoma Program at the Aflac Cancer and Blood Disorders Center, Children's Healthcare of Atlanta, Winship Cancer Institute at Emory University.

Brentuximab vedotin was the first antibody–drug conjugate developed for classic Hodgkin lymphoma. Several studies have demonstrated that incorporating the therapy into frontline treatment improves progression-free survival and overall survival. Despite improved outcomes, there are still serious side effects; relapses can occur.

"There is definitely a need to improve frontline therapies for Hodgkin lymphoma, particularly because a disproportionate number of patients with this disease are teens and young adults," Herrera added.

PD-1 checkpoint inhibitors are a powerful and growing form of immunotherapy used to treat melanoma, kidney cancer, head and neck cancers, relapsed or difficult to treat Hodgkin lymphoma and other cancers. The PD-L1 protein is expressed on Hodgkin lymphoma tumor cells and aids the cancer by signaling to immune cells, such as T cells, to stop working against tumors.

Checkpoint inhibitors block the PD-L1 protein to help the immune system and, specifically, T cells, do what they're designed to do, eradicate cancer. In this study, adding nivolumab to chemotherapy worked so well that some patients experienced remission after only a few treatments.

Next steps for the trial include following patients to measure the durability of progression-free survival, overall survival and other patient outcomes.

More information: Trial: www.swog.org/clinical-trials/s1826

Provided by SWOG Cancer Research Network

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