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## **New treatment shows long-term remission in patients with follicular non-Hodgkin's lymphoma**

Patients with a form of lymphatic cancer who received a new combination of chemotherapy and targeted radiation (radio immunotherapy) lived significantly longer than patients treated with standard chemotherapy alone on previous trials. Five-year follow-up data from the Phase II trial was published in the Sept. 1 edition of the Journal of Clinical Oncology.

Patients in the trial, known as **S9911**, were being treated for advanced follicular non-Hodgkin's lymphoma, a form of cancer that affects the blood, bone marrow and lymphatic tissues. The American Cancer Society estimates that 58,870 new cases of non-Hodgkin's lymphoma will be diagnosed in 2006 and that 18,840 will die from it. About 14 percent of the non-Hodgkin's lymphoma patients have follicular lymphoma.

The long-term follow-up data from the Phase II clinical trial shows that five years after the new treatment, 87 percent of the patients survived and 67 percent of the patients survived without their disease progressing. In comparison, using historical data, only 64 percent were still alive and 44 percent survived without disease progression after five years on the standard chemotherapy treatment.

The new treatment piggy-backs onto the standard treatment by delivering a one-two punch to the cancer cells, explained Oliver Press, M.D., who led the study for the Southwest Oncology Group (SWOG), one of the largest cancer clinical trials cooperative groups in the United States. The standard therapy uses a combination of four chemotherapy drugs known as CHOP – cyclophosphamide, doxorubicin, vincristine and prednisone. Patients in the trial received six 21-day treatment cycles of CHOP. Those who tolerated the treatment without progression were given the new treatment, tositumomab and Iodine-I 131 tositumomab. Tositumomab is an antibody developed in mice which binds to the CD20 antigen, found on the surface of normal and malignant B lymphocytes. The radiolabeled antibody delivers Iodine-I 131 directly to the cancer cells. Tositumomab/Iodine-I 131 tositumomab is marketed under the trade name BEXXAR® by GlaxoSmithKline.

“We feel that the five-year results of the trial are tremendously encouraging and some of the best ever observed in a SWOG clinical trial for patients with advanced follicular non-Hodgkin's lymphoma,” said Dr. Press, who is a member of the Fred Hutchinson Cancer Research Center, professor of medicine at the University of Washington and chairman of the scientific advisory board of the Lymphoma Research Foundation.

“While patients usually respond initially to CHOP therapy, most patients eventually recur. We feel that this new combination of drugs with antibodies such as tositumomab/Iodine-I 131 tositumomab show real promise. Not only are patients living longer, they seem to be living relatively symptom-free after the conclusion of their therapy,” Press said. The Phase II study was conducted at 34 SWOG institutions with 90 patients who have advanced-stage non-Hodgkin's lymphoma but had not been previously treated for the disease.

### **Results of S9911 prompts new Phase III study, S0016**

The initial success of the SWOG Phase II trial, known as **S9911**, prompted SWOG to open a Phase III intergroup trial in 2001 known as **S0016**. The Phase III trial is still open for registration to patients who have never been treated for follicular non-Hodgkin's lymphoma and whose disease expresses the CD20 antigen. The Cancer and Leukemia Group B (CALGB) and Eastern Cooperative Oncology Group (ECOG) are also participating in this study.

**(More)**

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The Phase III study compares CHOP plus BEXXAR to CHOP plus a different targeted antibody, Rituximab. The study was initially designed to compare three types of treatment – CHOP, CHOP plus Rituximab, and CHOP plus Tositumomab and Iodine-I 131. However, the CHOP-only arm of the study was closed Dec. 15, 2002, based on results from several completed clinical trials that demonstrated significantly improved response rates and progression-free survival in the CHOP-plus-Rituximab arm compared to CHOP alone, making CHOP plus Rituximab the new standard therapy.

The 17 patients on the Southwest Oncology Group trial **S0016** were accrued to the CHOP-only arm before the survival data comparing the CHOP-plus-Rituximab arm and the CHOP-only arm were known. “Now the goal is to determine which antibody – rituximab or the radiolabeled tositumomab antibody – produces the best results when combined with CHOP,” Press said. “This study is currently open to accrual and we encourage treating physicians and their patients to join us in completing this important clinical trial.” He noted that another radiolabeled antibody, ibritumomab tiuxetan (Zevalin), is being studied by other investigators.

### About the Southwest Oncology Group

The Southwest Oncology Group is one of the largest cancer clinical trials cooperative research groups in the United States. SWOG is a network of more than 5,000 physician-researchers located at nearly 550 institutions. In addition to their regular medical practices, Group investigators work together on clinical trials funded by the National Cancer Institute, part of the National Institutes of Health, to prevent and treat cancer in adults. SWOG enrolls nearly 7,200 patients each year and has about 120 clinical trials underway at any given time. The Southwest Oncology Group Headquarters Office is at the University of Michigan in Ann Arbor, Mich., the Operations Office is in San Antonio, Texas, and the Statistical Center is in Seattle, Wash.

For more information about these trials and the study enrollment criteria for **S0016**, contact the Southwest Oncology Group at [protocols@swog.org](mailto:protocols@swog.org) or 210-450-8808. For more information about the Southwest Oncology Group or to arrange an interview with study leaders, contact [Rosanne Fohn](#) at 210-450-8808.

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