

Phase III results show rituximab excels against pediatric Burkitt lymphoma

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Results of the phase III Inter-B-NHL-ritux 2010 clinical trial reported today in the *New England Journal of Medicine* show 95 percent three-year survival for pediatric patients with advanced B-cell non-Hodgkin lymphoma treated with the addition of anti-cancer immunotherapy rituximab to standard chemotherapy. The trial represents a major international collaboration between the European Intergroup for Childhood Non-Hodgkin Lymphoma (EICNHL) and the Children's Oncology Group (COG), and was led in the United States by Thomas Gross, MD, Ph.D., University of Colorado Cancer Center investigator and pediatric oncologist at Children's Hospital Colorado, and in Europe by Véronique Minard-Colin, MD and Catherine Patte, MD, both pediatric oncologists at the Gustave Roussy Department of Child and Adolescent Oncology in Paris, France. The addition of rituximab decreased treatment failures by 70 percent resulting in a 10 percent increase in the three-year survival rate seen with chemotherapy alone (LMB protocol).

"These outstanding results support rituximab as a new standard-of-care therapy for young patients with advanced B-cell non-Hodgkin lymphoma," Gross says.

Rituximab attaches to a protein called CD20 found on the surface of cancerous and healthy B-cells, helping the body's immune system to recognize and attack these cells. The drug previously earned FDA approval for use in combination with chemotherapy in adult patients with B-cell non-Hodgkin lymphoma. Though Burkitt lymphoma is the

most common form of pediatric non-Hodgkin lymphoma, it is a [rare disease](#) requiring collaboration of institutions in 13 countries to identify and treat enough [young patients](#) to effectively test the benefit of adding rituximab. In all, the Inter-B-NHL ritux 2010 phase III randomized trial involved 328 patients, age 2-18 years, treated in 176 centers distributed over four continents (Europe, North America, Australia and Asia).

Gross says, "With more than 95 percent of kids alive and disease-free after three years, this looks like a cure for the vast majority of our patients, even those with the most advanced disease."

Burkitt lymphoma is one of the fastest growing cancers in humans, doubling in size every 1-2 days. It develops in the lymphatic system, meaning that it can form anywhere in the body, but is most often seen in areas with high concentrations of lymph nodes including the abdomen and neck.

"The Inter-B-NHL ritux 2010 trial is a fine example of international cooperation in academic clinical research, and shows the importance of public-private collaborations with the pharmaceutical industry," Gross says.

The study led to authorization of rituximab for children with B-cell non-Hodgkin lymphoma in Europe by the European Medicine Agency (EMA) and Dr. Gross is hopeful the FDA will use these results as the basis for approval in the United States of rituximab with this patient population.

Provided by CU Anschutz Medical Campus

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