A new immunotherapeutic agent for children and adolescents with advanced lymphoma

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The excellent results of the phase III international paediatric study, Inter-B-NHL ritux 2010, have been published today in the *New England Journal of Medicine*. This academic trial involved two international cooperative groups—the European Intergroup for Childhood Non-Hodgkin Lymphoma (EICNHL) and the Children's Oncology Group (COG). It establishes a new standard treatment with an improved cure rate for children with advanced non-Hodgkin lymphoma, mainly Burkitt lymphoma. It supports the value of an immunotherapeutic agent, which was authorised in March 2020 by the European Commission for the treatment of a rare childhood cancer.

"With a three-year survival rate exceeding 95%, these results are outstanding. This study changes the international treatment bench-mark in young patients with advanced B-cell non-Hodgkin lymphoma," said Dr. Véronique Minard-Colin, paediatrician at the Gustave Roussy Department of Child and Adolescent Oncology in France who coordinated this major international trial with Dr. Thomas G. Gross currently at Children's Hospital Colorado in the United States.

The management of children with Burkitt lymphoma has improved considerably over recent decades. Cure rates have risen from 30% in the 1980s to higher than 85% with chemotherapy alone (LMB protocol) with no major late sequelae associated with the medication or the disease. This conventional LMB treatment was established more than 30 years ago by Dr. Catherine Patte, paediatric oncologist at Gustave Roussy and her French collaborators. However, despite this advance, about 15% of

children continued to die of this condition.

Rituximab is a monoclonal anti-CD20 antibody directed against lymphoma cells. This immunotherapeutic agent, developed by Roche, is indicated in combination with chemotherapy as a treatment for adults with malignant non-Hodgkin lymphoma. The international Inter-B-NHL-ritux 2010 clinical trial evaluated rituximab in children and adolescents by means of a Paediatric Investigation Plan in the context of European Paediatric Regulation.

As Burkitt lymphoma is a rare disease (~1000/1200 new cases/year in Europe and in the US), 12 countries collaborated to address the question as to whether rituximab would increase survival of children and young adults. The Inter-B-NHL ritux 2010 phase III randomised trial was conducted between December 2011 and November 2015 and involved 328 patients age 2-18 years, treated in 176 centres distributed over four continents (Europe, North America, Australia and Asia). It assessed the effects of addition of rituximab to standard LMB chemotherapy in high-risk B-cell non-Hodgkin lymphoma (the majority with Burkitt lymphoma).

When rituximab is administered with chemotherapy, more than 95% of children and adolescents with advanced Burkitt lymphoma remain alive and disease-free after more than three years of follow-up. This new combined therapy increases overall survival by around 10% and reduces the rate of occurrence of an event (death, relapse, tumour progression, second cancer, etc.) by 70%.

Aggressive B-cell non-Hodgkin lymphoma is a cancer which develops in the lymphatic system, carrier of immune cells throughout the body. It can develop in any part of the body. It is most frequently seen in the abdomen and neck, areas which harbour many lymph nodes. It is one of the most aggressive cancers and grows very rapidly although it is rare

and affects both children and adults. It is the most common lymphoma in children, accounting for more than 60% of paediatric non-Hodgkin lymphoma.

Cancers are fortunately rare in childhood, but this means that the development of new drugs to treat them must be conducted internationally. The Inter-B-NHL ritux 2010 trial is an excellent example of an international cooperation of academic clinical research in childhood cancer and of the importance of public-private collaborations with the pharmaceutical industry, so that positive findings result in marketing authorisation. The trial was run as part of a Paediatric Investigation Plan. Rituximab (MabThera) has been authorised in Europe since March 2020 for the treatment of children with high-risk B-cell non-Hodgkin lymphoma. It will be available for all children and costs will be reimbursed through the health systems of member states and beyond.

More information: Véronique Minard-Colin et al, Rituximab for High-Risk, Mature B-Cell Non-Hodgkin's Lymphoma in Children, *New England Journal of Medicine* (2020). DOI: 10.1056/NEJMoa1915315

Provided by Comprehensive Cancer Centre Gustave Roussy

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