

# Children's Oncology Group

## Statement from the Children's Oncology Group (COG) regarding recently released early results of a clinical trial for children with high-risk Neuroblastoma.

We wish to communicate important information about COG's protocol *ANBL0032, Phase III Randomized Study of Chimeric Antibody 14.18 (Ch14.18) in High Risk Neuroblastoma Following Myeloablative Therapy and Autologous Stem Cell Rescue*.

After careful review of the early ANBL0032 results made available through our independent Data and Safety Monitoring Committee, we have determined that the immunotherapy (experimental) arm of the study – a combination of ch14.18 antibody, cytokines (IL2 and GM-CSF) and Isotretinoin (also called Accutane or commonly abbreviated as cisRA) – more effectively reduces the risk that neuroblastoma will grow back than treatment with cisRA alone. We have also determined that the immunotherapy as specifically delivered on COG ANBL0032 increases the chance of survival after completion of therapy including stem cell transplantation when compared to treatment with cisRA alone. We now expect that this immunotherapy may eventually become a standard part of high-risk neuroblastoma treatment after stem cell transplant.

Because of these early results, we must stop further randomization for patients who will be enrolled on ANBL0032. All future patients who meet the strict eligibility requirements to enroll on ANBL0032 will receive immunotherapy (ch14.18 antibody and cytokines) in addition to cisRA. The study is currently on clinical hold by the FDA following investigation of observed toxicities.

Several hundred patients had to complete this study before these results could be known and verified. We are releasing this information now that we have been able to confirm that the result is real. Prior to obtaining this result, no one knew for certain whether the addition of ch14.18 antibody and cytokines to cisRA would help improve the survival of patients, or if it would merely add to the side effects of the overall treatment. This randomized study was the only way to answer this question and we thank all of the participants.

We fully understand that this information may raise questions and concerns among those patients who were previously enrolled in COG ANBL0032 and their parents, as well as for all children and families dealing with a diagnosis of high-risk neuroblastoma. For patients with neuroblastoma, your primary oncologist best knows your (child's) physical and treatment history and we strongly encourage you contact him/her to discuss any and all questions you may have. In addition, the Children's Oncology Group and the National Cancer Institute are planning to release treatment recommendations to physicians based on these results in the very near future. Trial participants and their families will be receiving information about these treatment recommendations from their primary oncologist. We have decided to publicly release the trial results before we have finalized the treatment recommendations so families need not become aware of this important information about the ANBL0032 clinical trial from other sources.

We are very grateful to the patients and their families who consented to participate in this important trial. Their involvement has been crucial to increasing our understanding of how to treat this disease and how to improve treatment options for future patients with high-risk neuroblastoma.

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