UPDATE MAY 2017

IMMUNOTHERAPY SHORTAGE FOR HIGH-RISK NEUROBLASTOMA

Immunotherapy Shortage for High-Risk Neuroblastoma

High-risk neuroblastoma is an aggressive childhood cancer that predominantly afflicts children under the age of ten years. Neuroblastoma arises from the developing sympathetic nervous system, predominantly in the abdomen and chest, and spreads throughout the body. In New Zealand, on average, 4 to 6 children are diagnosed with high-risk neuroblastoma every year.

High-risk neuroblastoma requires intensive and prolonged therapy that takes approximately 18 months to deliver. Treatment is divided into three phases:

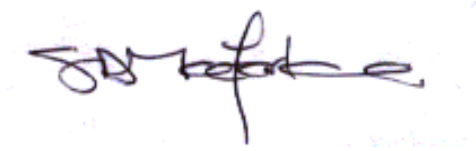
1) Chemotherapy and surgery
2) High-dose chemotherapy with autologous stem cell transplantation and radiation
3) Immunotherapy with Dinutuximab, and cis-retinoic acid.

Immune therapy uses a medicine called “dinutuximab” (Unituxin, ch14.18), a FDA-approved chimeric monoclonal antibody that targets a molecule called “GD2” on the surface of neuroblastoma cells. Dinutuximab directs the patients’ own immune system to kill neuroblastoma cells. Dinutuximab prolongs survival of children with high-risk neuroblastoma and is considered the standard of care.

In New Zealand dinutuximab was originally provided to children who were participating in a clinical trial. The pivotal clinical trial was stopped earlier than anticipated because on average, children randomly selected to receive dinutuximab lived longer than children who did not receive the medicine (Yu et al, NEJM 2010).

At the conclusion of the clinical trial, United Therapeutics Corporation (UTC) provided dinutuximab to New Zealand and Australia at no charge as part of an expanded access program. UTC recently advised New Zealand and Australia that the expanded access program was ending due to a global shortage of dinutuximab.

New Zealand has made formal enquires to UTC, and an alternative European supplier of an equivalent agent (Dinutuximab Beta), to ask if either company will supply New Zealand on a commercial basis. We can now confirm that Dinutximab Beta will be available where clinically appropriate as a fully funded chemotherapeutic agent. This means that the entire range of treatment for Neuroblastoma standard of care will continue to be fully funded in New Zealand.



Scott Macfarlane
National Clinical Leader - Child Cancer, National Child Cancer Network