

MEDIA RELEASE

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New international collaboration to offer hope to paediatric blood cancer patients

- **New clinical trial offers options for children and teenagers who relapse with acute lymphoblastic leukaemia (ALL)**
- **First Australia-wide ALL clinical trial collaboration with St Jude Children’s Research Hospital (USA)**
- **Co-funded by the Leukaemia Foundation and Snowdome Foundation**

A new innovative clinical trial, titled RAVEN will soon be available in Australia, giving hope to children and teenagers who relapse with acute lymphoblastic leukaemia (ALL).

The Phase II RAVEN trial will be the first study to examine the effectiveness of venetoclax and navitoclax in a large number of children and teenagers with relapsed ALL.

While more than 80 per cent of children and teenagers with ALL will be cured with frontline treatment, 10-20 per cent will relapse. Unfortunately, the chance of survival for those with relapsed leukaemia remains significantly lower. Patients with relapsed ALL often experience resistance to conventional chemotherapy which limits effective treatment options.

Originally developed by St Jude Children’s Research Hospital in Memphis (U.S.), RAVEN will be available Australia-wide and co-funded equally by the Leukaemia Foundation and Snowdome Foundation. It marks the eighth project the two organisations have co-funded to improve outcomes for blood cancer patients.

Leukaemia Foundation CEO Chris Tanti welcomed the international collaboration as an important step in offering renewed hope for children and young people who relapse with ALL.

“This trial will enable immediate access to a new treatment option that is desperately needed for children who are not responding to conventional chemotherapy, and we are very happy to be doing this in collaboration with the Snowdome Foundation,” Mr Tanti said.

“Clinical trials not only offer a renewed hope, they have the power to revolutionise the way we treat blood cancer in Australia and achieve our goal of zero lives lost to blood cancer by 2035.”

Kirstee Macbeth, Snowdome Foundation CEO, said the trial will not only explore a new promising treatment but also help open up more international collaborations into the future. Media Release \

“Thanks to investment in medical research and clinical trials, survival rates for childhood leukemias have improved remarkably. However, for those who have relapsed, the needle has not moved significantly

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enough and there are very few treatment options available. That's why support from Snowdome and our donors allows researchers to push forward, to focus on solving the biggest challenges and accelerate the discovery of new therapies."

"We are very proud to partner with the Leukaemia Foundation in providing this research grant to paediatric centres across Australia. This funding is a critical step in advancing new and better treatments for children battling with cancer, improving their chances for survival and quality of life," Ms Macbeth said.

Principal Investigator on the trial and consultant paediatric and haematologist/oncologist at the Women's and Children's Hospital, Adelaide, Dr Michael Osborn said the aim of the trial was to determine whether venetoclax and navitoclax, added to chemotherapy, will improve the rate of patients who are measurable residual disease (MRD) negative at the end of induction.

"High-quality clinical trials are vital to improve clinical care for patients and international partnerships are essential due to the rarity of childhood cancers. We couldn't have opened this study in Australia without the support of the Leukaemia Foundation and Snowdome Foundation."

"Venetoclax has been shown to be highly effective in a number of haematological malignancies in older adults, such as chronic lymphocytic leukemia and certain lymphomas. The recently completed Phase I study of this combination in ALL demonstrated very promising early results, highlighting the need to test the effectiveness of this combination in a larger number of children. The combination of these two drugs – venetoclax and navitoclax – together with chemotherapy and other successful immunotherapies, like blinatumomab, and targeted agents makes this trial unique."

"If this is shown to be effective, it will offer potential treatments for patients who've run out of other options. We anticipate there will be just over 10 children and young people across Australia per year who would be eligible for this trial, but hope that what we learn from this study will benefit many more," Dr Osborn said.

The RAVEN trial, designed to treat patients aged four to 21, with a combination of venetoclax, navitoclax, and chemotherapy, will recruit up to 78 patients in Australia, New Zealand, and the U.S.

Genomic testing will also be undertaken as part of the RAVEN study in part at the South Australian Health and Medical Research Institute (SAHMRI) in Adelaide, providing an opportunity to collaborate with St Jude's and further develop diagnostic tests in partnership with one of the best ALL genomics labs in the world.

The Australian and New Zealand Children's Haematology/Oncology Group (ANZCHOG) will be the national sponsor for RAVEN. The trial is due to open in Australia in mid-2022 and is expected to recruit participants over the following 30 months. The trial is anticipated to be available at Royal Children's Hospital (VIC), Monash Children's Hospital (VIC), Perth Children's Hospital (WA), John Hunter Children's Hospital (NSW), Children's Hospital at Westmead (NSW), Sydney Children's Hospital (NSW) and Women's & Children's Hospital (SA). Available for interview:

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