

MEDIA RELEASE

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Australian researchers stopping melanoma in its tracks

A team of Australian researchers has made the ultimate move in the battle to beat melanoma, successfully trialling a combination of new treatments to stop the disease in its tracks and prevent it from spreading or metastasising to distant organs.

Melanoma is the deadliest form of skin cancer, with one Australian dying from advanced melanoma every five hours.

Ground-breaking results from two international clinical trials conducted by investigators at Melanoma Institute Australia are being presented today at one of the world's largest medical oncology conferences, the European Society for Medical Oncology (ESMO) 2017 Congress in Spain. The research has also been published in the prestigious *New England Journal of Medicine* today.

The trials, *COMBI-AD* and *CheckMate 238*, proved successful in preventing the spread of disease in Stage III melanoma patients whose tumours had been surgically removed. Until now, these patients were at a high risk (40–70 per cent) of their disease progressing to advanced and fatal melanoma.

“These results will change the way we treat melanoma patients as well as their quality of life,” says study author Professor Georgina Long, Conjoint Medical Director of Melanoma Institute Australia and Chair of Melanoma Medical Oncology and Translational Research at The University of Sydney.

“Until now, Stage III melanoma patients who have had their tumours surgically removed have simply had to play the waiting game, to see if their melanoma would metastasise or spread. Living with such fear severely affected them and their loved ones.

“Results from these clinical trials suggest we can stop the disease in its tracks – effectively preventing it from spreading and saving lives. Our ultimate goal of making melanoma a chronic rather than a terminal illness is now so much closer to being achieved,” she said.

In the *COMBI-AD* trial, patients were randomised to receive a combination of targeted therapies (dabrafenib and trametinib) or placebo for 12 months. Targeted therapies block the action of a particular gene which is a driver for melanoma. It was aimed at patients who are BRAF positive. It not only prevented resected Stage III melanoma from recurring, but it increased overall survival.

The *CheckMate 238* trial involved patients with high risk Stage III and Stage IV disease who had had all melanoma surgically removed. They were randomised to be treated with the immunotherapy nivolumab or ipilimumab for 12 months. Immunotherapies reboot the immune system to attack the melanoma cells. Results showed nivolumab decreased the chance of relapse, and it had a superior safety profile over ipilimumab. This benefit was seen in patients regardless of BRAF mutation status. The follow up period is too short to yet determine long-term survival rates.

Research had already shown that targeted and immune therapies can successfully treat patients with advanced (Stage IV) melanoma that could not be removed surgically.

These clinical trials are the first in the world to give the treatments to melanoma patients at an earlier stage of the disease to prevent spread and recurrence.

“These clinical trials show we now have ammunition to prevent melanoma spreading and progressing, which until now was a critical area of disease behaviour where we had no control,” Professor Long said.

“This will change how melanoma is treated around the world, as we no longer have to passively wait to see if the melanoma spreads.

“We can now actively and effectively attack the melanoma at an earlier stage, reducing the dreadful anxiety for patients about progressing to a potentially terminal illness and ensuring they have much better outcomes,” she said.

Publications:

- Long G.V, *et al.* Adjuvant Dabrafenib Plus Trametinib for Stage III BRAF V600E/K–Mutant Melanoma. *New England Journal of Medicine.*
- Weber, J. *et al.* Adjuvant Nivolumab Versus Ipilimumab in Resected Stage III/IV Melanoma. *New England Journal of Medicine.*

FOR MORE INFORMATION AND INTERVIEWS, CONTACT:

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BACKGROUND INFORMATION:

Melanoma

- In 2009, the 1-year survival rate for patients with Stage IV melanoma was only 30 per cent. With advances in medical research, today we are seeing survival rates of up to 75 per cent.
- Australia has one of the highest incidences of melanoma in the world and melanoma is often referred to as “Australia’s national cancer”.
- Almost 14,000 Australians are expected to be diagnosed with melanoma in 2017 and more than 1,800 Australians are expected to die from melanoma.
- One Australian dies from melanoma every five hours.
- While 90 per cent of people with melanoma are able to be cured by having the primary melanoma cancer removed through surgery, the cancer spreads in the other 10 per cent because it is detected too late.

Melanoma Institute Australia

- Melanoma Institute Australia (MIA) pioneers advances in melanoma research and treatment that are making a difference to the lives of patients today.
- MIA is a non-profit organisation dedicated to preventing and curing melanoma through innovative, world-class research, treatment and education programs.

- MIA is a national affiliated network of melanoma researchers and clinicians based in Sydney at The Poche Centre – the world’s largest melanoma research and treatment facility. It is from here that our specialists pioneer new research, conduct clinical trials, develop new treatments and promote awareness of melanoma and where our clinics treat melanoma patients.

COMBI-AD Trial

- The COMBI-AD Trial is a double-blind, placebo-controlled, Phase III study. 870 patients with completely resected, high-risk, Stage III BRAF V600E/K–mutant melanoma were randomized 1:1 to receive dabrafenib 150 mg twice daily plus trametinib 2 mg once daily or two matching placebos for 12 months.
- The trial found that with a median follow-up of 2.8 years, dabrafenib plus trametinib significantly prolonged relapse-free survival vs placebo with a risk reduction of 53%. The combination also improved overall survival (risk reduction 43%), distant metastasis-free survival and freedom from relapse. The safety profile of dabrafenib and trametinib was consistent with that observed in metastatic melanoma.

CheckMate 238 Trial

- The CheckMate 238 Trial is a double-blind Phase III study. 906 patients were randomized 1:1 to receive nivolumab 3 mg per kilogram every 2 weeks or ipilimumab 10 mg per kilogram every 3 weeks for 4 doses, then every 12 weeks, up to 1 year.
- The trial found that at a minimum follow-up of 18 months, nivolumab significantly improved recurrence-free survival versus ipilimumab (risk reduction 35%).
- Previously, ipilimumab had been shown to reduce the risk of recurrence compared with placebo by 24% in patients with resected stage III melanoma.

About ESMO

- The European Society for Medical Oncology (ESMO) 35th Annual Congress is being held in Madrid Spain 8–12 September.
- It brings oncology professionals together to facilitate interaction and bridge knowledge sharing between the laboratory and clinic.
- The aim of ESMO 2017 is to work together, aligning the objectives of researchers and clinicians, in order to provide more precise direction leading to better treatment options for cancer patients.
- The annual ESMO Congress is the most prestigious and influential oncology platform in Europe.