

RESULTS PUBLISHED OF LONGEST AND LARGEST STUDY OF STAGE III MELANOMA PATIENTS RECEIVING TARGETED THERAPY FOR POST-SURGERY TREATMENT

Study shows five-year outcome of patients who received Canada's only approved adjuvant treatment for stage III melanoma patients to prevent relapse after surgery

Toronto, ON: June 19, 2020 – Save Your Skin Foundation is pleased to share the conclusions of a five-year study that followed 870 patients with BRAF-mutated melanoma who were treated with a combination therapy of Tafinlar (dabrafenib) plus Mekinist (trametinib) following the surgical removal of their cancer. The findings show that more than half of the patients in the study were alive and free of a relapse after five years.¹

Researchers from the study reported that more than half of patients treated with adjuvant Tafinlar + Mekinist were alive and relapse-free at five years. Compared to 36% of patients in the study's placebo arm who were alive and relapse-free at the time of this analysis, this is a considerable improvement.

The results of the study, known as the COMBI-AD clinical trial, demonstrate that treatment with Tafinlar (dabrafenib) and Mekinist (trametinib) following the surgical removal of melanoma offers a long-term and durable relapse-free survival (RFS) benefit to high-risk patients diagnosed with stage III, BRAF-mutation positive melanoma. The results were presented at this year's American Society of Clinical Oncology's [Virtual Scientific Program](#). This study represents the largest collection of data and longest follow-up to date in this patient population treated with targeted therapy.

"These results can help inform treatment decisions for patients with BRAF V600 melanoma," said Dr. Mike Smylie, Medical Oncologist, Cross Cancer Institute, Edmonton, AB. "The COMBI-AD findings show that for resected BRAF+ melanoma patients, treatment with Tafinlar + Mekinist offers the chance of long-term relapse-free survival."

"This study is so important because melanoma patients face a known high risk of relapse after their cancer has been surgically removed," says Natalie Richardson, Managing Director of Save Your Skin Foundation, and stage III melanoma survivor. "When I had resection surgery for my melanoma, there were no available treatments for stage III patients like me. I was lucky enough to get treatment through a clinical trial. Now, because of research like this, stage III melanoma patients have better options."

About the COMBI-AD Study²

COMBI-AD is a pivotal Phase III study evaluating Tafinlar (dabrafenib) + Mekinist (trametinib) among patients with stage III, BRAF V600E/K-mutant melanoma without prior anticancer therapy.

It is a two-arm, randomized, double-blind Phase III study of dabrafenib in combination with trametinib versus two placebos in the adjuvant treatment of melanoma after surgical resection. Patients with completely resected, histologically confirmed, BRAF V600E/K mutation-positive, high-risk [stage IIIa

¹ <https://www.newswire.ca/news-releases/long-term-relapse-free-survival-data-for-high-risk-stage-iii-melanoma-patients-treated-with-tafinlar-r-mekinist-r-following-surgery-presented-at-asco20-811449605.html>

² <https://clinicaltrials.gov/ct2/show/NCT01682083?term=COMBI-AD&draw=2&rank=1>

(lymph node metastasis >1 mm), IIIb or IIIc] cutaneous melanoma were screened for eligibility. Subjects were randomized to receive either dabrafenib (150 mg twice daily) and trametinib (2 mg once daily) combination therapy or two placebos for up to one year. The primary end point is recurrence-free survival, and secondary endpoints include overall survival, distant metastasis-free survival, freedom from relapse analysis and safety.

About Tafinlar® + Mekinist®

The combination of Tafinlar + Mekinist is approved in Canada to treat patients with unresectable or metastatic melanoma who have a BRAF V600 mutation and for the adjuvant treatment of patients with BRAF V600 mutation melanoma and involvement of lymph nodes, following complete surgical removal of the tumours⁸.

About Save Your Skin Foundation

Save Your Skin Foundation (SYSF) is a patient-led not-for-profit organization dedicated to the fight against non-melanoma skin cancers, melanoma, and ocular melanoma through education, advocacy, and awareness initiatives across Canada. SYSF is dedicated to providing a community of oncology patient and caregiver support throughout the entire continuum of care, from prevention and diagnosis to survivorship. Please visit saveyourskin.ca for more information.

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