Long-term, relapse-free survival data for high-risk, stage III melanoma patients treated with Tafinlar® + Mekinist® following surgery presented at ASCO20

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- More than half of patients with BRAF-mutated advanced melanoma treated with Tafinlar + Mekinist were alive and free of a relapse at five years[1]
- Study conclusions drawn from the five-year follow-up of a dataset of 870 patients with BRAF-mutated melanoma treated with targeted therapy following the surgical removal of their cancer[1,2]

Dorval, Quebec, June 16, 2020 – Novartis has announced updated results from the landmark COMBI-AD clinical trial, demonstrating 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[1]. These findings from the longest follow-up, at 60 months, and largest dataset to date of patients with Stage III melanoma receiving targeted therapy for adjuvant treatment, were presented at the ASCO20 Virtual Scientific Program (Abstract #10001)[1].

The COMBI-AD study results are drawn from a prospective analysis of 870 patients with BRAF V600-mutated melanoma treated with Tafinlar + Mekinist following surgery[1]. Researchers reported that more than half (52%;95% CI, 48%-58%) of patients treated with adjuvant Tafinlar + Mekinist were alive and relapse-free at five years[1]. Among patients in the study's placebo arm 36% (95% CI, 32%-41%) were alive and relapse-free at the time of this analysis, generally consistent with typical melanoma relapse-free survival rates seen among patients with resected stage III disease without treatment[1,3-5].

"These results are highly encouraging for stage III melanoma patients. We have evidence that shows treatment with Tafinlar + Mekinist after surgical resection gives melanoma patients the chance for long-term relapse-free survival," said Dr. Elaine McWhirter, Staff Medical Oncologist at the Juravinski Cancer Centre (JCC) in Hamilton and Associate Professor at McMaster University. "The COMBI-AD findings are important for patients and physicians because they give us a window into managing resected BRAF+ melanoma patients, especially as our priority is to prevent the cancer from reaching vital organs."

This study represents the largest collection of data and longest follow-up to date in this patient population treated with targeted therapy[2].

"The reason this data is so important is because melanoma patients are still at risk even after surgery. The COMBI-AD data shows a 49% risk reduction in melanoma relapse or death," said Daniel Hébert Country Medical Head, Oncology, Novartis Pharmaceuticals Canada Inc. "When it comes to ongoing research, our goal at Novartis is to continue to reimagine cancer to bring new approaches and treatment options to patients and physicians to help improve and extend people's lives in different disease areas, including melanoma."

Researchers additionally reported the five-year COMBI-AD analysis showed:

- Median RFS, or the length of time when 50% of patients are still alive and relapse-free, was not yet

reached at the five -year data cut-off for patients on Tafinlar + Mekinist treatment, suggesting long-term benefit of targeted therapy in the adjuvant (post-surgical) setting (NR; 95% CI, 47.9 mo-NR)[1].

- Median RFS was 16.6 months for patients taking a placebo (95% CI, 12.7-22.1 mo)[1].
- Treatment with Tafinlar + Mekinist reduced the risk of relapse or death by 49% compared to placebo (hazard ratio [HR] 0.51; 95% CI 0.42, 0.61)[1].

“Research in the adjuvant setting is vital, particularly as cases of melanoma continue to climb in Canada,” said Falyn Katz, Executive Director, Melanoma Network of Canada. “A chance at improving long-term survival following surgery is what patients and their loved ones need and truly hope for. The data that we are seeing from ASCO is tremendous!”

About the COMBI-AD Study[1,2,6,7&]

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 (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.

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 tumours[8].

Tafinlar® (dabrafenib) + Mekinist® (trametinib) Important Safety Information

The full prescribing information for Tafinlar® and Mekinist® can be found at: https://www.novartis.com/ca-en/.

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