

PRESS RELEASE

8:30am AEDT, 20 January 2023

“International clinical trial demonstrates improved survival with new treatment for patients with advanced gastro-oesophageal cancer”

Results presented today at the 2023 ASCO Gastrointestinal Cancers Symposium (ASCO GI)

SUMMARY

- Analysis from the randomised phase III, double-blind placebo-controlled INTEGRATE IIa study demonstrated regorafenib significantly improved overall survival (OS) in patients with refractory advanced gastro-oesophageal carcinoma (AGOC).
- This international trial was led by the Australasian Gastro-Intestinal Trials Group (AGITG) and conducted by the NHMRC Clinical Trials Centre (NHMRC CTC).
- Regorafenib is the first oral multi-targeted tyrosine kinase inhibitor (TKI) to demonstrate improved overall survival in a mixed population of Asian and non-Asian patients with metastatic or locally recurrent gastro-oesophageal cancer.
- Regorafenib is a compound developed by Bayer which provided drug and funding for the trial. The study was conducted independently of Bayer.

ANNOUNCEMENT

The AGITG and NHMRC CTC today announced that the INTEGRATE IIa study, a phase III trial evaluated regorafenib for the treatment of patients with advanced gastro-oesophageal cancer (AGOC), has met its primary endpoint of a statistically significant improvement in overall survival of about 30%. The phase III INTEGRATE IIa study evaluated the efficacy and safety of regorafenib in patients with AGOC, whose disease has progressed after a minimum of two lines of prior anti-cancer therapy for recurrent/metastatic disease. The safety and tolerability were generally consistent with the known profile of regorafenib. Detailed efficacy and safety analyses from this study were presented today at the 2023 ASCO Gastrointestinal Cancers Symposium (ASCO GI).

The AGITG is leading a study currently conducted by the NHMRC CTC, a multinational phase III study called INTEGRATE IIb, which is further investigating the

combination of regorafenib and nivolumab, compared to standard chemotherapy alone.

ABOUT

The INTEGRATE IIa study is an international, double blind, placebo-controlled trial with 2:1 (regorafenib:placebo) randomisation of patients with evaluable gastro-oesophageal adenocarcinoma in the third line setting or later line. To be enrolled in the study, patients must have failed or been found intolerant to a minimum of two lines of prior anti-cancer therapy, including a platinum agent and a fluoropyrimidine analogue.

The study randomised 251 patients from 40 recruiting sites across six countries worldwide, including North America and Asia. Patients were randomised to receive either regorafenib 160mg or placebo, with best supportive care provided to each arm.

GASTRIC CANCER: PROFILE

Gastric cancer is currently the fifth most common cancer (5.6% of all new cases), and the fourth most common cause of cancer-related deaths worldwide (7.7% of all deaths).^{1, 2} For AGOC there remains a poor prognosis, with chemotherapy or biologic therapy in the refractory setting associated with a median overall survival of less than six months and real-world data in stage IV disease associated with a 2-year overall survival of less than 10%.^{3, 4}

INSTITUTION PROFILES

About the Australasian Gastro-Intestinal Trials Group

The Australasian Gastro-Intestinal Trials Group (AGITG) is Australia and New Zealand's peak body for GI cancer research. It is the only not-for-profit organisation in the region dedicated to improving the health and quality of life of patients with GI cancer by developing and conducting impartial and collaborative multi-disciplinary research. More background information is available at www.gicancer.org.au.

About NHMRC Clinical Trials Centre

The NHMRC Clinical Trials Centre (NHMRC CTC) is a flagship research centre based at the University of Sydney. It runs studies designed to improve global health outcomes by bringing together world leading experts in healthcare, clinical trials, and related research methods.

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