

Letter to Editor

Response to 'Dai W et al. Am J Cancer Res 2015;5(10):3270-3275' from the makers of nintedanib

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We are writing as representatives of Boehringer Ingelheim (BI) to express our concern over an article recently published in the American Journal of Cancer Research.

Dai et al. 2015 [1] report the results of a study conducted in China in 62 patients with advanced non-small-cell lung cancer (NSCLC) after progression following first-line platinum-based chemotherapy. The article states that patients received a treatment claimed to be nintedanib as a monotherapy treatment. It is reported that the study accrued patients between January 2011 and February 2013 with a median treatment duration of 11.2 months, and a median follow-up after treatment of 12.4 months.

In this letter we would like to clarify that this study was not sponsored by BI either at the global or local level. Furthermore, this study was not a BI-reviewed or BI-approved investigator-initiated study, for which BI would provide either support or access to nintedanib. BI did not supply nintedanib for this study, and neither could nintedanib have been independently purchased commercially by the investigators. This is known because nintedanib was not commercially available until after October 2014 in the US when the first regulatory approval of nintedanib for idiopathic pulmonary fibrosis (IPF) was granted by the Food and Drug Administration (FDA), and after November 2014 in the EU, when the first regulatory approval of nintedanib for NSCLC was granted by the European Medicines Agency (EMA). Both approvals occurred long after the patient

recruitment period reported in the manuscript (January 2011 to February 2013) and as such, nintedanib would not have been available to be independently purchased by the investigators.

As a company, BI has approached the study investigators to enquire as to the origin of the drug. The investigators, however, were not able to produce records of how the clinical supplies for the study were obtained and could not provide information on the specifics of the drug used in the study. We are therefore confident that this study did not use the BI-produced molecule nintedanib (Vargatef®). It is our opinion that the information published in this article is not representative of the known safety and efficacy profile of nintedanib in NSCLC.

The currently approved oncology indication for nintedanib in the EU and in several countries worldwide is in combination with docetaxel for the treatment of adult patients with locally advanced, metastatic or locally recurrent NSCLC of adenocarcinoma tumour histology after first-line chemotherapy. This approval was obtained based on the results of the randomised, double-blind, placebo-controlled, Phase III trial LUME-Lung 1 that compared the combination of nintedanib and docetaxel with docetaxel alone in patients with advanced NSCLC who had previously received first-line chemotherapy [2]. In the LUME-Lung 1 trial, treatment with nintedanib significantly extended survival in patients with adenocarcinoma from a median overall survival of 10.3 months in the placebo arm to 12.6 months in the nintedanib arm (HR 0.83, 95% CI 0.70-0.99,

p=0.036). Outside of oncology, nintedanib is also approved as monotherapy for the treatment of patients with IPF in the USA, EU and in several Asian countries. However, nintedanib is not currently approved by the China Food and Drug Administration (CFDA) for use in China in either indication.

BI believes that the readership of the American Journal of Cancer Research should be made aware of the facts summarized above. Therefore, BI respectfully requests that at its earliest convenience, the American Journal of Cancer Research acknowledges the concerns raised above by formally publishing this communication in the journal and cross-referencing it to any future access of the article in question.

Disclosure of conflict of interest

The authors of this letter are employees of Boehringer Ingelheim.

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References

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