PRESS RELEASE VARGATEF® (nintedanib*)

Ingelheim, Germany, (27 November 2014) – Today Boehringer Ingelheim announced that the European Commission has granted EU marketing authorisation for VARGATEF® (nintedanib*), valid for the 28 countries within the EU. VARGATEF® in combination with docetaxel is indicated for use in adult patients with locally advanced, metastatic or locally recurrent non-small cell lung cancer (NSCLC) of adenocarcinoma tumour histology, after first-line chemotherapy.

"The approval of nintedanib offers a much needed new treatment option for adult lung cancer patients with advanced adenocarcinoma in the second-line setting," commented PD. Dr Martin Reck, Head of Department of Thoracic Oncology, Lung Clinic Grosshansdorf, Germany and lead investigator of the LUME-Lung 1 trial. "The clinical data has shown that patients receiving nintedanib plus docetaxel experienced over one year overall survival with no further compromise to their quality of life, compared to docetaxel alone."

Adenocarcinoma is the most common type of lung cancer and the majority of patients are diagnosed in an advanced stage.2 Most patients will experience disease progression during or after first-line chemotherapy and there is a significant unmet need for new, effective second-line treatments.3 "We are delighted by the European Commission's decision to approve VARGATEF® in the EU and feel extremely proud that our long standing commitment to oncology research and development has brought a new option to lung cancer patients with this specific type of disease," said Professor Klaus Dugi, Chief Medical Officer, Boehringer Ingelheim. "The approval of VARGATEF® expands our oncology portfolio, following last year's approval of GIOTRIF® (afatinib) for another specific type of lung cancer. In the idiopathic pulmonary fibrosis indication, nintedanib has recently been approved by the U.S. FDA."

The approval of nintedanib*, a triple angiokinase inhibitor, is based on the outcomes of the LUME-Lung 1 clinical trial which enrolled 1,314 patients with NSCLC, after first-line chemotherapy.1 Data from the study, published in Lancet Oncology (Feb 2014), demonstrated that compared to docetaxel alone, nintedanib* when added to docetaxel significantly extended median overall survival from 10.3 to 12.6 months (p=0.0359; HR: 0.83) for patients with adenocarcinoma, with a quarter of patients surviving for two years or more (survival at 24 months – nintedanib* plus docetaxel, 25.7% of patients vs. placebo plus docetaxel, 19.1% of patients, p=0.0359; HR: 0.83).1 Nintedanib* demonstrated a manageable adverse event profile without further compromising patients' overall health-related quality of life.

Adding nintedanib* to docetaxel did not significantly increase discontinuation rates, compared to docetaxel alone.1 Nintedanib* is an oral, twice-daily treatment and is the second approved compound in the Boehringer Ingelheim oncology portfolio. GIOTRIF® (afatinib**) was the first oncology drug from the portfolio to be approved to treat non-small cell lung cancer patients with distinct types of EGFR-mutation positive NSCLC.

References

1. Reck M, Kaiser R, Mellemgaard A, et al. Docetaxel plus nintedanib versus docetaxel plus placebo in patients with previously treated non-small cell lung cancer (LUME-Lung 1): a phase 3, double-blind, randomised controlled trial. Lancet Oncol 2014;15:143–55.

2. Howlader N, et al. SEER Cancer Statistics Review, 1975-2011, National Cancer Institute. Bethesda, MD, http://seer.cancer.gov/csr/1975_2011/, based on November 2013 SEER data submission, posted to the SEER website, April 2014.

3. Hilberg F, Roth GJ, Krssak M, et al. BIBF1120: triple angiokinase inhibitor with sustained receptor blockade and good anti-tumor efficacy. Cancer Res 2008;68: 4774-82