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ASIA EDITION

Boehringer seeks EU marketing nod for cancer drug

October 18, 2013 | Regulatory | By BioSpectrum Bureau

Singapore: Boehringer Ingelheim has submitted a marketing authorization application to the European Medicines Agency (EMA) for the approval of its oral triple angiokinase inhibitor nintedanib, in combination with docetaxel, for the treatment of patients with locally advanced, metastatic or recurrent non-small cell lung cancer (NSCLC).

Nintedanib, when added to chemotherapy, is a lung cancer treatment that extended patient survival beyond one year in a broad population of adenocarcinoma patients, after initial chemotherapy had failed.

The EU marketing authorization application for the approval of nintedanib is based on the international, double-blind, phase III LUME-Lung 1 trial, which was the first trial to show a survival benefit of an add-on treatment in a broad second line adenocarcinoma patient population versus an active comparator (standard-of-care/chemotherapy).