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Boehringer Ingelheim Initiaties Pivotal Trial on Volasertib* for Acute Myeloid Leukaemia

Boehringer Ingelheim invests in rare diseases with high unmet medical need. Volasertib* is in Phase III clinical development for acute myeloid leukaemia and nintedanib* is in Phase III clinical development for idiopathic pulmonary fibrosis.

With the enrollment of the first patient, Boehringer Ingelheim is pleased to announce on international Rare Disease Day, the initiation of a Phase III study (POLO-AML-2) investigating volasertib*, a selective and potent polo-like kinase (Plk) inhibitor, in combination with chemotherapy, in patients with acute myeloid leukaemia (AML) ineligible for intensive therapy.

Acute leukaemias are rare diseases, with AML being the most deadly acute leukaemia in adults.[1] 28 February, 2013 marked the sixth international Rare Disease Day, and more than 60 countries around the world have joined to raise awareness for those affected by rare diseases. In Europe, rare disease is defined as a life-threatening or chronically debilitating disease which affects fewer than five people per 10, 000.[2]

Professor Klaus Dugi, Corporate Senior Vice President Medicine, Boehringer Ingelheim

"Rare diseases are often incorrectly diagnosed and even once they are correctly diagnosed, there is often a lack of viable treatment options" said Professor Klaus Dugi, Corporate Senior Vice President Medicine, Boehringer Ingelheim. "The initiation of the POLO-AML-2 trial is a significant milestone as therapeutic options are limited in AML patients ineligible for intensive therapy."

AML is characterised by the rapid proliferation of abnormal blood precursor cells that accumulate in the bone marrow and interfere with the production of normal blood cells. The primary endpoint of POLO-AML-2 is objective response to the combination treatment compared to the chemotherapy alone. The main secondary endpoint of POLO-AML-2 is overall survival.

The study was initiated following positive results from a Phase II study which demonstrated higher rates of

objective response and an improvement in event free survival in patients receiving volasertib* in combination with chemotherapy versus chemotherapy alone.[3]

"Boehringer Ingelheim is committed to developing innovative medications that improve patients' lives and has put considerable effort into research and development of treatments for orphan† diseases." said Professor Klaus Dugi, Corporate Senior Vice President Medicine, Boehringer Ingelheim.

In addition to AML, Boehringer Ingelheim is investigating therapeutic approaches for other rare diseases including idiopathic pulmonary fibrosis (IPF). IPF is a severely debilitating and fatal respiratory disease. It is characterised by progressive loss of lung function ultimately leading to the death of half of the patient population two to three years after diagnosis.

Nintedanib*, a small molecule tyrosine kinase inhibitor (TKI), targets growth factor receptors which have been shown to be potentially involved in the pathomechanism of pulmonary fibrosis. The pivotal INPULSISTM-1 and INPULSISTM-2 Phase III trials have completed recruitment and are ongoing in study centres worldwide to assess the clinical outcomes in IPF patients treated with nintedanib*. The Phase III INPULSIS trials aim to build upon the promising results of the Phase II TOMORROW trial, which demonstrated a positive trend in reducing lung function decline in IPF patients treated with 150 mg of nintedanib* twice daily when compared to placebo.[4] Additionally, nintedanib* has received orphan-drug designation from the U.S. Food and Drug Administration in June 2011 and by the Ministry of Health, Labour and Welfare of Japan in September 2011.

For more information about Rare Disease Day, please visit www.rarediseaseday.org

References

1. Deschler B, et al. Acute Myeloid Leukemia: Epidemiology and Etiology. Cancer. 2006. 2009-2107
2. European Commission. Available at: http://ec.europa.eu/health/ph_information/documents/ev20040705_rd05_en.pdf. [Last accessed: February 2013]
3. Döhner H, Phase I/II study of volasertib (BI 6727), an intravenous Polo-like kinase (Plk) inhibitor, in patients with acute myeloid leukemia (AML): results from the randomized phase II part for volasertib in combination with low-dose cytarabine (LDAC) versus LDAC monotherapy in patients with previously untreated AML ineligible for intensive treatment. Oral Presentation at ASH Annual Meeting and Exposition 2012
4. Richeldi L, et al. Efficacy of a tyrosine kinase inhibitor in idiopathic pulmonary fibrosis. N Engl J Med. 2011;365(12):1079-87

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