Boehringer Ingelheim initiates first Phase III clinical trial in Ovarian Cancer

Boehringer Ingelheim

Ingelheim/Germany, 17 December 2009 – Boehringer Ingelheim announced today the initiation of a new phase III clinical trial to evaluate one of its two late-stage oncology pipeline compounds for the treatment of patients with advanced ovarian cancer. The clinical study, called LUME-Ovar-1 trial, investigates the compound BIBF 1120, a novel oral anti-angiogenic agent [*], for its efficacy and safety as first-line treatment in combination with standard chemotherapy compared to placebo in combination with standard chemotherapy in patients with advanced ovarian cancer.

The LUME–Ovar 1 trial / AGO-OVAR 12
AGO-OVAR 12 or LUME-Ovar 1 is an intergroup study conducted by an international consortium of study groups led by the AGO Study Group (Arbeitsgemeinschaft Gynaekologische Onkologie Study Group, Germany), and Boehringer Ingelheim. BIBF 1120 (planned brand name Vargatef™) is a novel oral compound that works by simultaneously inhibiting three receptors involved in the formation of blood vessels, a process also called angiogenesis, which is needed for tumours to grow and spread.

“Anti-angiogenic compounds are one of the most promising new approaches in treating cancer, and ovarian cancer appears to be particularly sensitive to these novel agents, as suggested by early clinical trials.” said Andreas du Bois, MD, PhD, of AGO Study group and International Coordinating Investigator of this trial. “BIBF 1120 inhibits several aspects of the pathway that controls the growth of new blood vessels, and it has already been shown to be both effective and well tolerated in previous trials, including a recently completed phase II trial of BIBF 1120 in ovarian cancer."

The AGO Study group has already performed a phase I/II study and developed the combination now evaluated. "Based on our good experience with this combination," said Dr. Philipp Harter MD , of AGO study group and principal investigator of the starting trial, "we look forward to continue investigating this novel compound in ovarian cancer patients in the first line setting.”

The decision to progress BIBF 1120 into a phase III trial in ovarian cancer was based on previous study results which indicate that the agent may be both efficacious and well tolerated as maintenance therapy in patients with relapsed ovarian cancer who had responded to prior chemotherapy. Data presented this year at the annual meeting of the American Society of Clinical Oncology (ASCO) showed that in the trial women with ovarian cancer treated with BIBF 1120 were less likely to experience progression of their disease compared to those treated with placebo: at 36 weeks, 14.3% of women taking BIBF 1120 were progression-free compared to 5% of women taking placebo. [1] This phase II trial represents the first published

randomised, placebo controlled data of an anti-angiogenic agent in ovarian cancer.

As angiogenesis plays a pivotal role in the growth of all solid tumours, BIBF 1120 is currently being investigated in a number of cancers including advanced non-small cell lung cancer (NSCLC), colorectal cancer (CRC), renal cell cancer (RCC) und hepatic cell cancer (HCC).

BIBF 1120 is one of Boehringer Ingelheim's most advanced compounds along with BIBW 2992 (planned trade name Tovok™), both of which are currently in phase III development for the treatment of patients with advanced non-small cell lung cancer, a patient population with limited treatment choices.

LUX-Lung 1 Trial: Development progress with BIBW 2992
In the clinical development of the compound BIBW 2992, a milestone has been reached recently. The company completed patient recruitment for a Phase III Lung cancer trial, the LUX-Lung 1 trial. LUX-Lung 1 investigates BIBW 2992 (planned brand name Tovok™) plus best supportive care (BSC) versus placebo plus BSC in non-small cell lung cancer patients who have experienced a failure of treatment with erlotinib or gefitinib (EGFR TKI failures).

Boehringer Ingelheim believes in evidence-based, scientific progress; its extensive oncology clinical trial programme involves more than 800 study centers in 47 countries. Boehringer Ingelheim has a dedicated cancer research center in Vienna where scientists are focused on the discovery and development of new treatments to combat or alleviate cancer.

About Ovarian Cancer
Ovarian cancer often goes undetected until an advanced stage, and is sometimes referred to as the "silent killer". According to the 2008 World Health Organization World Cancer Report, as of 2002, ovarian cancer was ranked as the 6th most common cancer in women, and is considered the most lethal of gynaecological malignancies. Approximately 204,000 new cases were diagnosed worldwide and 125,000 women died from the disease in 2002. [2] The ACS estimates that about 21,550 new cases of ovarian cancer were diagnosed in the United States (U.S.) during 2008. Only forty-five percent of women with ovarian cancer are still alive five years after diagnosis in the U.S. [3]

About AGO
The AGO Study group is a German cooperative study group active in clinical research in gynecological oncology for almost 20 years with great experience in developing and optimizing therapeutic standards in first and second line treatment of ovarian cancer. Together with other European and overseas cooperative study groups, AGO has developed the current standard regimens.

About Boehringer Ingelheim in Oncology
Building on scientific expertise and excellence in the fields of pulmonary and cardiovascular medicine, metabolic disease, neurology, virology and immunology, Boehringer Ingelheim has embarked on a major research programme to develop innovative cancer drugs. Working in close collaboration with the international

scientific community and a number of the world's leading cancer centers, Boehringer Ingelheim is committed to discovering and developing novel cancer treatments. This commitment is underpinned by using advances in science to develop a range of targeted therapies in areas of medical need, including various solid tumours and haematological cancers.

The current focus of research includes compounds in three areas: angiogenesis inhibition, signal transduction inhibition and cell-cycle kinase inhibition. BIBW 2992 is currently in Phase III clinical development in NSCLC, and was granted Fast Track designation for a third/fourth line treatment indication in NSCLC by the US Food & Drug Administration. In addition, the LUME-Lung Phase III clinical trial program, which is investigating BIBF 1120 in combination with standard second-line chemotherapy treatments for patients with advanced NSCLC, is ongoing. In the area of cell-cycle kinase inhibition, Boehringer Ingelheim is developing inhibitors of polo-like kinase 1 (Plk1), a protein that is involved in the processes of cell division. These molecules are in the early stages of clinical development.

Boehringer Ingelheim
The Boehringer Ingelheim group is one of the world's 20 leading pharmaceutical companies. Headquartered in Ingelheim, Germany, it operates globally with 138 affiliates in 47 countries and 41,300 employees. Since it was founded in 1885, the independent, family-owned company has been committed to researching, developing, manufacturing and marketing novel products of high therapeutic value for human and veterinary medicine.

In 2008, Boehringer Ingelheim posted net sales of 11.6 billion euro while spending one fifth of net sales in its largest business segment Prescription Medicines on research and development.

* An anti-angiogenic agent inhibits angiogenesis, the process of formation of vessels toward the tumour. The vessel supplies the tumour with oxygen and nutritions to enable its further growth, a pre-requisite for the tumour to spread.

SOURCE [1]

Links:
[1] http://www.boehringer-ingelheim.com/news/news_releases/press_releases/2009/17_december_2009.html