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Investor News

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Bayer and Orion Initiate Phase III Trial of Novel Prostate Cancer Agent ODM-201 in Men with High-Risk Non-Metastatic Castration-Resistant Prostate Cancer

Leverkusen, September 16, 2014 – Bayer HealthCare and Orion Corporation, a pharmaceutical company based in Espoo, Finland, have begun to enroll patients in a Phase III trial with ODM-201, an investigational novel oral androgen receptor (AR) inhibitor in clinical development for the treatment of patients with prostate cancer. The study, called ARAMIS, evaluates ODM-201 in men with castration-resistant prostate cancer (CRPC) who have rising Prostate-Specific Antigen (PSA) levels and no detectable metastases. The trial is designed to determine the effects of the treatment on metastasis-free survival (MFS).

“The field of treatment options for prostate cancer patients is evolving rapidly. However, once prostate cancer becomes resistant to conventional anti-hormonal therapy, many patients will eventually develop metastatic disease,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “The initiation of a Phase III clinical trial for ODM-201 marks the starting point for a potential new treatment option for patients whose cancer has not yet spread and is an important milestone for Bayer in our ongoing effort to meet the unmet needs of people affected by cancer.”

Earlier this year, Bayer and Orion had entered into a global agreement under which they will jointly develop ODM-201, with Bayer contributing a major share of the costs of future development. Bayer will commercialize ODM-201 globally and Orion has the option to co-promote ODM-201 in Europe. Orion will be responsible for the manufacturing of the product.

About the ARAMIS trial

The ARAMIS trial is a randomized, Phase III, multicenter, double-blind, placebo-controlled trial evaluating the safety and efficacy of oral ODM-201 in patients with non-metastatic CRPC who are at high risk for developing metastatic disease. About 1,500 patients are planned to be randomized in a 2:1 ratio to receive 600mg of ODM-201 twice a day or matching placebo. Randomization will be stratified by PSA doubling time (PSADT ≤ 6 months vs. > 6 months) and use of osteoclast-targeted therapy (yes vs. no).

The primary endpoint of this study is metastasis-free survival (MFS), defined as time between randomization and evidence of metastasis or death from any cause. The secondary objectives of this study are overall survival (OS), time to first symptomatic skeletal event (SSE), time to initiation of first cytotoxic chemotherapy, time to pain progression, and characterization of the safety and tolerability of ODM-201.

About Castration-Resistant Prostate Cancer (CRPC)

Prostate cancer is the second most commonly diagnosed malignancy in men worldwide. In 2012, an estimated 1.1 million men were diagnosed with prostate cancer, and about 307,000 died from the disease worldwide. Prostate cancer is the fifth leading cause of death from cancer in men.

Prostate cancer results from the abnormal proliferation of cells within the prostate gland, which is part of a man´s reproductive system. Prostate cancer mainly affects men over the age of 50, and the risk increases with age.

Treatment options for prostate cancer range from surgery to radiation treatment to therapy using hormone-receptor antagonists, i.e. substances that stop the formation of testosterone or prevent its effect at the target location. However, in nearly all cases, the cancer will become resistant to conventional hormone therapy.

Castration-resistant prostate cancer (CRPC) is an advanced form of prostate cancer and is characterized by persistent, high-level androgen receptor (AR) function and resistance to conventional anti-androgens. The field of treatment options for castration-resistant patients is evolving rapidly. There is no standard treatment for CRPC patients who have rising Prostate-Specific Antigen (PSA) levels during androgen-deprivation therapy and no detectable metastases. In men with progressive non-metastatic CRPC, a short PSA doubling time has been consistently associated with reduced time to first metastasis and death.

About ODM-201

ODM-201 is an investigational novel androgen receptor (AR) inhibitor with unique chemistry that is designed to block the growth of prostate cancer cells. ODM-201 binds to the AR with high affinity and inhibits receptor function by blocking its cellular function. In nonclinical models, ODM-201 has shown to only minimally penetrate the blood-brain barrier.

A Phase II clinical trial conducted in patients with progressive metastatic castration-resistant prostate cancer assessed the efficacy and safety of three dose levels of ODM-201 (100mg, 200mg and 700mg given twice a day) in 124 patients. The study included patients who were treated previously with abiraterone and/or chemotherapy as well as patients who were chemotherapy-naïve. The results showed that ODM-201 provided disease suppression and had a favorable safety profile. The results were presented at the international ECCO oncology congress at the end of September 2013 and published in June 2014 in *The Lancet Oncology*.

About Oncology at Bayer

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

About Orion

Orion is a globally operating Finnish company developing pharmaceuticals and diagnostic tests – a builder of well-being. Orion develops, manufactures and markets human and veterinary pharmaceuticals, active pharmaceutical ingredients and diagnostic tests. The company is continuously developing new drugs and treatment methods. Pharmaceutical R&D focuses on central nervous system drugs, oncology and critical care drugs, and Easyhaler® pulmonary drugs.

Orion's net sales in 2013 amounted to EUR 1,007 million, and the company had about 3,500 employees. Orion's A and B shares are listed on NASDAQ OMX Helsinki.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen, Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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