Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

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Bayer and Orion Corporation to develop and commercialize novel prostate cancer treatment

Leverkusen, Germany, June 2, 2014 – Bayer has entered into a global agreement with Orion Corporation, a pharmaceutical company based in Espoo, Finland, (Nasdaq OMX Helsinki: ORNAV and ORNBV) for the development and commercialization of the compound ODM-201, an investigational novel oral androgen receptor inhibitor. ODM-201 is in clinical development for the treatment of patients with prostate cancer. Bayer and Orion plan to start jointly the clinical Phase III program to further evaluate the efficacy and safety of ODM-201 in patients with non-metastatic castration-resistant prostate cancer (nm-CRPC) in 2014. These patients are at high risk of developing metastatic disease and can be identified due to rapid Prostate Specific Antigen (PSA) increases.

“We see in ODM-201 a potential new treatment for patients with high risk non-metastatic castration-resistant prostate cancer and are looking forward to developing this promising compound,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Bayer’s oncology portfolio currently includes Xofigo which has been shown to prolong life in patients with castrate resistant prostate cancer with symptomatic bone metastases, and no known visceral metastases. From a clinical perspective, ODM-201 has the potential to complement our portfolio in prostate cancer and enables us to deliver new treatment options for patients who desperately need them.”

"Joining forces with Bayer, I believe that we have again achieved a collaboration that represents the best of all worlds," said Dr. Reijo Salonen, SVP R&D and Chief Medical Officer for Orion. “Bayer has recently committed to developing therapies in Oncology, particularly for prostate cancer. At Orion, we continue our track record of inventing innovative molecules. And most importantly, for patients with prostate cancer, this partnership will bring a medicine that will make an important difference to their lives."

Under the terms of the agreement, Bayer and Orion 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. Orion will receive an upfront payment of EUR 50 million and is eligible to receive cash payments from Bayer upon achievement of certain development, tech transfer and commercialization milestones, as well as tiered double-digit royalties on future global net sales. Orion will use the majority of the up-front payment this year against the costs of the Phase III study to be started this year.

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 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 AR function and resistance to conventional anti-androgens such as bicalutamide. The field of treatment options for castrate-resistant patients is evolving rapidly.

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, or were chemotherapy-naïve. The results showed that ODM-201 had high anticancer activity in all patients. Eighty-six percent of patients who had not received earlier chemotherapy or abiraterone experienced a >50% PSA decrease at week 12 on dose level 700 mg twice a day. ODM-201 was well tolerated in all patients, including patients who had received chemotherapy and abiraterone. The results were presented at the international ECCO oncology congress at the end of September 2013.

About Xofigo™ (radium-223 dichloride)

Xofigo™ with the active ingredient radium-223 dichloride (radium-223) is an alpha particle-emitting radioactive therapeutic agent with an anti-tumor effect on bone metastases. Radium-223 mimics calcium and forms complexes with the bone mineral hydroxyapatite at areas of increased bone turnover, such as bone metastases. The high linear energy transfer of alpha emitters may cause double-strand DNA breaks in adjacent cells, resulting in an anti-tumor effect on bone metastases. The alpha particle range from radium-223 is less than 100 micrometers, which may limit damage to the surrounding normal tissue.

Xofigo is approved by the European Commission for the treatment of adults with CRPC, symptomatic bone metastases and no known visceral metastases. In the U.S., it is approved for the treatment of CRPC patients with symptomatic bone metastases and no known visceral metastatic disease.

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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Dr. Olaf Weber (+49-214-30-33567)

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