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Investor News

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Bayer Initiates Phase III Trial of Radium-223 Dichloride in Combination with Abiraterone Acetate for Patients with Metastatic Castration-Resistant Prostate Cancer

Leverkusen, Germany, April 2, 2014 – Bayer HealthCare today announced that the company has begun to enroll patients in a new Phase III trial with radium-223 dichloride (radium-223, Xofigo®). The study evaluates radium-223 in combination with abiraterone acetate and prednisone/prednisolone for the treatment of asymptomatic or mildly symptomatic chemotherapy-naïve patients with bone predominant metastatic castration-resistant prostate cancer (CRPC). The trial is designed to determine the effects of this combination treatment on symptomatic skeletal event-free survival (SSE-FS).

“Radium-223 has a specific mode of action and has already demonstrated safety and efficacy in CRPC patients with symptomatic bone metastases and no known visceral metastases. We welcome further exploration of treatment combinations and pathways that may extend these benefits in even more men with this disease as the treatment landscape continues to evolve rapidly,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

Radium-223 has been approved under the brand name Xofigo® 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.

Abiraterone acetate, a product of the Janssen Pharmaceutical Companies, is a prescription medicine that is used along with prednisone and is available in more than 80 countries. Abiraterone acetate is the prodrug of abiraterone that works by inhibiting the CYP17 enzyme complex in the androgen biosynthesis pathway which is important in the production of testosterone and other androgens. This pathway is also present in the testes, adrenal gland and the prostate tumor tissue. In the EU, it is marketed under the

brand name Zytiga® and indicated with prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer in adult men who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy in whom chemotherapy is not yet clinically indicated or whose disease has progressed on or after a docetaxel based chemotherapy regimen.

Phase III Trial Design

The randomized double-blind, placebo-controlled Phase III trial will investigate whether providing radium-223 dichloride (radium-223) in combination with abiraterone acetate and prednisone/prednisolone will increase symptomatic skeletal event free survival (SSE-FS). The trial will enroll approximately 800 patients who will be randomized in a 1:1 ratio to receive study treatment (either radium-223 dichloride or placebo in addition to abiraterone acetate plus prednisone/prednisolone and best supportive care for the first six cycles followed by abiraterone acetate plus prednisone/prednisolone thereafter) until an on-study symptomatic skeletal event (SSE) occurs (or other withdrawal criteria are met).

The international study will be sponsored by Bayer and conducted in collaboration with Janssen Research and Development in various regions including sites in Europe, the U.S., Australia, Brazil and Japan. For further information about the study, please visit www.clinicaltrials.gov.

About Castration-Resistant Prostate Cancer (CRPC) and Bone Metastases

Prostate cancer is the second most commonly diagnosed malignancy in men worldwide. In 2012, an estimated 1,111,000 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.

Castration-resistant prostate cancer (CRPC) is an advanced form of prostate cancer. A majority of men with CRPC have symptomatic bone metastases resulting in pain, skeletal events such as fractures or spinal cord compression, and/or reduced survival. In fact, bone metastases lead to an increased risk of morbidity and death in patients with CRPC.

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.

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 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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