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Investor News

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Bayer Receives U.S. FDA Approval for Cancer Treatment Xofigo® (radium 223 dichloride) Injection

- New treatment for castration-resistant prostate cancer (CRPC) patients with bone metastases
- Xofigo shown in a pivotal Phase III trial to significantly improve overall survival

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Leverkusen, Germany, May 15, 2013 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) approved Xofigo® (radium 223 dichloride) for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease. Xofigo is the first alpha particle-emitting radioactive therapeutic agent approved by the FDA that has demonstrated improvement in overall survival (OS) and delay in time to first symptomatic skeletal event (SSE) compared to placebo, as shown in the pivotal Phase III ALSYMPCA trial.

The commercial production of Xofigo is underway, and first doses are expected to be ready for patient treatment within a few weeks. Bayer has worldwide exclusive marketing rights for Xofigo. In the U.S., Bayer HealthCare and Algeta US, LLC will co-promote the product.

“Xofigo shows a favorable safety profile and has the potential to improve patient outcomes in a completely novel way. Radium 223 emits alpha particles that affect cancer cells in bone metastases and may contribute to a survival improvement,” said Kemal Malik, MD, member of the Bayer HealthCare Executive Committee and Head of Global Development. “This FDA approval will provide prostate cancer patients and the physicians who care for them with a new and innovative treatment option.”

“Most men with advanced prostate cancer develop bone metastases, which can be life-threatening,” said Oliver Sartor, MD, North American Principal Investigator for the pivotal trial and medical director of the Tulane Cancer Center. “Xofigo has demonstrated an anti-tumor effect on bone metastases and an overall survival effect in prostate cancer, making it an important addition to the treatment of CRPC patients.”

Bone is the most common site in the body to be affected by metastatic cancer and bone metastases are particularly prevalent in patients with prostate cancer. Approximately 90% of patients with metastatic prostate cancer show evidence of bone metastases. Bone metastases can lead to an increase in frequency of skeletal events and have been shown to be the main cause of morbidity and death in patients with CRPC.

Efficacy and Safety Data Supporting Xofigo Approval

The approval of Xofigo (radium 223 dichloride, radium 223) is based on data from the pivotal Phase III ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) trial. At the interim analysis, radium 223 significantly improved overall survival (OS) [HR=0.695 (95% CI 0.552-0.875), p=0.00185]; median OS was 14.0 months with radium 223 plus best standard of care vs. 11.2 months with placebo plus best standard of care. Additionally, at the interim analysis there was a delay in the time to first symptomatic skeletal event (SSE) for patients treated with radium 223 vs. placebo.

An updated analysis, conducted after the study was unblinded, showed a further improvement in overall survival (OS) for patients treated with radium 223 vs. placebo, with a median OS of 14.9 months vs. 11.3 months; HR=0.695 (95% CI 0.581-0.832).

The most common adverse reactions (greater than or equal to 10%) in patients receiving radium 223 in the ALSYMPCA trial were nausea, diarrhea, vomiting and peripheral edema. The most common hematologic laboratory abnormalities (greater than or equal to 10%) were anemia, lymphocytopenia, leukopenia, thrombocytopenia and neutropenia.

About Xofigo® (radium 223 dichloride) Injection

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.

Radium 223 is currently not approved by the European Medicines Agency (EMA) or other authorities outside the U.S. Bayer submitted a Marketing Authorization Application to the EMA for radium 223 in December 2012 for the treatment of CRPC patients with bone metastases.

In September 2009, Bayer signed an agreement with Algeta ASA (Oslo, Norway) for the development and commercialization of radium 223. Under the terms of the agreement, Bayer will develop, apply for health authority approvals worldwide and commercialize radium 223 globally. Algeta will co-promote radium 223 with Bayer in the U.S.

About the ALSYMPCA Trial

The ALSYMPCA trial was a Phase III, randomized, double-blind, placebo-controlled international study of radium 223 dichloride with best standard of care vs. placebo with best standard of care in symptomatic CRPC patients with bone metastases. The trial enrolled 921 patients in more than 100 centers in 19 countries. The study treatment consisted of up to six intravenous injections of radium 223 or placebo each separated by an interval of four weeks.

The primary endpoint of the study was overall survival (OS). A key secondary endpoint was time to first symptomatic skeletal event (SSE), as defined as external beam radiation therapy (EBRT) to relieve skeletal symptoms, new symptomatic pathologic bone fracture, occurrence of spinal cord compression, or tumor-related orthopedic surgical intervention.

About CRPC and Bone Metastases

Prostate cancer is the most common non-cutaneous malignancy in men worldwide. In 2008, an estimated 899,000 men were diagnosed with prostate cancer and 258,000 died from the disease worldwide. Prostate cancer is the sixth leading cause of death from cancer in men.

A majority of men with CRPC have radiological evidence of bone metastases. Once the cancer cells settle in the bone, they interfere with bone strength, often leading to pain, fracture and other complications that can significantly impair a man’s health. Bone metastases secondary to prostate cancer typically target the lumbar spine, vertebrae and

pelvis. In fact, bone metastases are the main cause of morbidity and death in patients with CRPC.

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 18.6 billion (2012), 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 55,300 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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