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Investor News

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Bayer Submits New Drug Application to U.S. FDA for Radium-223 Dichloride for the Treatment of Castration-Resistant Prostate Cancer with Bone Metastases

Radium-223 dichloride now submitted for Marketing Authorization in EU and US

Leverkusen, Germany, December 14, 2012 – Bayer HealthCare today announced that the company has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for radium-223 dichloride (radium-223) for the treatment of castration-resistant prostate cancer (CRPC) patients with bone metastases.

“This submission of radium-223 for the treatment of men with CRPC that has metastasized to the bone brings us closer to a new treatment option for patients in the U.S. dealing with this advanced form of cancer,” said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “We are looking forward to continuing discussions with the regulatory authorities to bring this innovative treatment option to patients as quickly as we can.”

Earlier this week, Bayer submitted a Marketing Authorization Application to the European Medicines Agency (EMA) for radium-223 for the treatment of castration-resistant prostate cancer patients with bone metastases.

The submission is based on data from the pivotal Phase III ALSYMPCA (ALpharadin in SYMptomatic Prostate CAncer) trial. In the study, radium-223 significantly increased overall survival by 44 percent (HR=0.695, p=0.00007), resulting in a 30.5 percent reduction in the risk of death compared to placebo. The median overall survival (OS) benefit in patients with radium-223 was 3.6 months, based on 14.9 months OS with radium-223 plus best standard of care (BSoC) vs. 11.3 months with placebo plus BSoC. These updated results were presented at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June 2012.

The most common hematologic adverse events for patients treated with radium-223 and best standard of care (BSoC) and compared to placebo and BSoC included anemia (31% vs. 31%), neutropenia (5% vs. 1%) and thrombocytopenia (12% vs. 6%). With respect to Grade 3 and 4 adverse events, the most common events included anemia (13% vs. 13%), neutropenia (2% vs. 1%) and thrombocytopenia (6% vs. 2%). The most common non-hematologic adverse events in patients treated with radium-223 and BSoC ompared to placebo and BSoC included bone pain (50% vs. 62%), nausea (36% vs. 35%), diarrhea (25% vs. 15%) and vomiting (19% vs. 14%). With respect to Grade 3 to 4 adverse events, the most common events included bone pain (21% vs. 26%).

About the ALSYMPCA Trial

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

The primary endpoint of the study was overall survival. Secondary endpoints included time to occurrence of skeletal related events (SRE), changes and time to progression in PSA and ALP, safety, and impact on quality of life measures.

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 Radium-223 Dichloride
Radium-223 dichloride (radium-223), formerly referred to as Alpharadin, is a therapeutic alpha particle-emitting pharmaceutical with targeted anti-tumor effect on bone metastases in development for 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 global health authority approvals, and commercialize radium-223 globally. Algeta will co-promote radium-223 with Bayer in the US. The ALSYMPCA trial was initiated by Algeta in June 2008.

Radium-223 is an investigational agent and is not approved by the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), or other health authorities.

In terms of further development activities for radium-223, Bayer intends to conduct studies in earlier settings of prostate cancer, including combination studies with other agents, as well as exploratory studies in other tumors such as breast cancer and osteosarcoma.

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

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 17.2 billion (2011), 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 55,700 employees

(Dec 31, 2011) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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