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Investor News

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Castration-Resistant Prostate Cancer with Bone Metastases:

Radium-223 Dichloride Granted Priority Review by U.S. FDA

Leverkusen, Germany, February 13, 2013 – Bayer HealthCare announced today that the U.S. Food and Drug Administration (FDA) has granted priority review to the New Drug Application (NDA) filed in December 2012 for the investigational oncology compound radium-223 dichloride (radium-223). The application is under review for the treatment of castration-resistant prostate cancer (CRPC) patients with bone metastases.

"We are pleased that the FDA has granted priority review status to radium-223 for the treatment of patients with CRPC that has metastasized to the bones as it supports our ongoing effort to make this compound available as early as possible for patients in need of new treatment options," said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The FDA grants priority review to medicines that offer major advances in care or that provide a treatment where no adequate therapy exists. Under the Prescription Drug User Fee Act (PDUFA), the FDA aims to complete its review within eight months from the submission of the NDA, rather than the standard 12-month review cycle.

The submission was 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.

In January 2013, the U.S. Nuclear Regulatory Commission (NRC) issued a licensing decision on the medical use of radium-223. The decision states that U.S. medical sites can procure and administer radium-223 under 10 CFR Part 35, Subpart E, which includes 10 CFR § 35.300.

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 prostate-specific antigen (PSA) and alkaline phosphatase (ALP), safety, and impact on quality of life measures.

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.

Radium-223 is an investigational agent and is not approved by the European Medicines Agency (EMA), the FDA, or other health authorities. Bayer has 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 global health authority approvals worldwide, and commercialize radium-223 globally. Algeta will co-promote radium-223 with Bayer in the U.S.

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 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. 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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