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Investor News

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Bayer Receives Recommendation for Approval of Radium Ra 223 Dichloride for the Treatment of Castration-Resistant Prostate Cancer with Bone Metastases in the European Union

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Leverkusen, Germany, September 20, 2013 – Bayer HealthCare today announced that the European Committee for Medicinal Products for Human Use (CHMP) recommended radium Ra 223 dichloride (radium-223) for approval with a proposed indication for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. The decision of the European Commission on the approval is expected in the fourth quarter of 2013. Radium-223 was approved by the U.S. Food and Drug Administration (FDA) in May under the brand name Xofigo®.

The CHMP recommendation is based on data from the pivotal Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) trial.

“This recommendation confirms the safety and efficacy of radium-223 as a potential treatment option for patients suffering from castration-resistant prostate cancer with bone metastases, a debilitating and potentially deadly condition,” said Christopher Parker, M.D., Principal Investigator of the ALSYMPCA trial and Consultant Clinical Oncologist at The Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, London. "There are many men with this disease who could benefit from the availability of radium-223 due to its unique ability to extend life and delay symptomatic skeletal events such as spinal cord compression and the need for external beam radiation therapy for bone pain.”

“We are encouraged by the Positive CHMP Opinion issued today, and look forward to providing radium-223 to patients with prostate cancer and bone metastases upon

approval of the European Commission," said Kemal Malik, M.D., Member of the Bayer HealthCare Executive Committee and Head of Global Development. "Radium-223 exemplifies Bayer's commitment to developing therapies with innovative mechanisms of action that can help address unmet patient needs."

About Castration-Resistant Prostate Cancer (CRPC) and Bone Metastases
Prostate cancer is the second most commonly diagnosed 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 symptomatic 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 one of the main causes of morbidity and death in patients with CRPC.

About Radium Ra 223 Dichloride
Radium Ra 223 dichloride (radium-223) is an alpha particle-emitting pharmaceutical. Its active moiety mimics calcium and selectively targets bone, specifically areas of bone metastases, by forming complexes with the bone mineral hydroxyapatite. The high linear energy transfer of alpha emitters (80 keV/micrometer) leads to a high frequency of double-strand DNA breaks in adjacent tumour cells, resulting in a potent cytotoxic effect. Additional effects on the tumour microenvironment including osteoblasts and osteoclasts also contribute to the in vivo efficacy. The alpha particle range from radium-223 is less than 100 micrometers (less than 10 cell diameters) which minimises damage to the surrounding normal tissue.

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 is co-promoting radium-223 (Xofigo® injection) with Bayer in the U.S.

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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