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Investor News

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Bayer Receives Approval for New Cancer Drug Xofigo® in the EU

- New treatment for adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases
- Xofigo significantly extended overall survival in Phase III ALSYMPCA study

Leverkusen, Germany, November 15, 2013 – Bayer HealthCare announced today that the European Commission (EC) has granted marketing authorisation for Xofigo® 1000 kBq/ml, solution for injection (radium Ra 223 dichloride) for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. This decision follows a positive recommendation from the European Committee for Medicinal Products for Human Use (CHMP) in September of this year. The approval of Xofigo is based on data from the pivotal Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **C**Ancer) trial.

“Bone metastases occur in the majority of men living with castration-resistant prostate cancer and can result in pain and even death. The profound impact of bone metastases should therefore be a key treatment consideration for this disease,” said Christopher Parker, M.D., Principal Investigator of the ALSYMPCA trial and Consultant Clinical Oncologist at The Royal Marsden NHS Foundation Trust, and Honorary Reader in Prostate Oncology at The Institute of Cancer Research, London. “Xofigo targets bone metastases, delivering a localized cytotoxic effect to offer patients prolonged survival, making it an exciting advance in the treatment of this cancer.”

“As the latest addition to Bayer’s growing oncology franchise and following a quick approval in the U.S., we are pleased that Xofigo is now available to patients in Europe,” said Kemal Malik, M.D., member of the Bayer HealthCare Executive Committee and Head of Global Development.

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 Xofigo[®] (radium Ra 223 dichloride)

Xofigo[®] is an alpha particle-emitting pharmaceutical. Xofigo's 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 Xofigo is less than 100 micrometers (less than 10 cell diameters), which minimises damage to the surrounding normal tissue.

Xofigo is approved in the U.S. for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

In September 2009, Bayer signed an agreement with Algeta ASA (Oslo, Norway) for the development and commercialization of Xofigo. Under the terms of this agreement, Bayer will develop, apply for health authority approvals worldwide and commercialize Xofigo globally. Algeta is co-promoting Xofigo 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 prioritises 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 54,900 employees (Dec 31, 2012) and is represented in more than 100 countries. More information at www.healthcare.bayer.com.

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