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Investor News

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Bayer Submits Marketing Authorization for Radium-223 Dichloride to Treat Prostate Cancer with Bone Metastases in Japan

Regulatory submission based on positive data from Phase III ALSYMPCA

Leverkusen, Germany, April 24, 2015 – Bayer HealthCare has submitted an application for marketing authorization to the Ministry of Health, Labour and Welfare (MHLW) in Japan for radium-223 dichloride (radium-223) solution for injection for the treatment of prostate cancer patients with bone metastases.

“The number of patients suffering from prostate cancer has steadily increased in Japan over the past years, and for patients with advanced disease, there are limited options,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “With its specific mode of action and the proven clinical benefit, radium-223 reflects our commitment to developing innovative cancer treatments for patients for whom only limited therapy options are available today.”

The regulatory submission is based on data from the pivotal Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) trial as well as data from additional trials to evaluate the safety and efficacy of radium-223 in Japanese patients. At the interim analysis of the ALSYMPCA trial, 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 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 (occurring at a rate of 10% or greater) in patients receiving radium-223 in the ALSYMPCA trial were nausea, diarrhea, vomiting and peripheral edema. The most common hematologic laboratory abnormalities (occurring at a rate of 10% or greater) were anemia, lymphocytopenia, leukopenia, thrombocytopenia and neutropenia.

About the ALSYMPCA Trial

The ALSYMPCA trial was a Phase III, randomized, double-blind, placebo-controlled international study of radium-223 with best standard of care vs. placebo with best standard of care in symptomatic castration-resistant prostate cancer (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 OS. A key secondary endpoint was time to first 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 Castration-Resistant Prostate Cancer (CRPC) and Bone Metastases

Prostate cancer is the second most commonly diagnosed malignancy in men worldwide. In 2012, an estimated 1,111,000 men were diagnosed with prostate cancer and 307,000 died from the disease worldwide. In Japan, an estimated 47,000 men were affected with prostate cancer and 12,000 died from the disease in 2013. Prostate cancer is the fifth leading cause of death from cancer in men worldwide, and the sixth leading cause of death from cancer in Japanese men.

CRPC is an advanced form of prostate cancer. A majority of men with CRPC have symptomatic bone metastases resulting in pain, skeletal events such as fractures or spinal cord compression, and/or reduced survival. In fact, bone metastases lead to an increased risk of morbidity and death in patients with CRPC.

About Radium-223 Dichloride

Radium-223 dichloride (radium-223) is a therapeutic alpha particle-emitting pharmaceutical with an anti-tumor effect on bone metastases. Radium-223 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 leads to a high frequency of double-strand DNA breaks in adjacent tumor cells, resulting in a potent cytotoxic effect. The alpha particle range from radium-223 is less than 100 micrometers, which minimizes damage to the surrounding normal tissue.

Radium-223 has been approved under the brand name Xofigo® in more than 40 countries worldwide, including the U.S. and the EU.

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 around EUR 20.0 billion (2014), 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 60,700 employees (Dec 31, 2014) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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