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Investor News

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Bayer Receives Approval for Xofigo[®] in Japan

Marketing authorization granted for the treatment of castration-resistant prostate cancer patients with bone metastases

Leverkusen, Germany, March 29, 2016 – Bayer announced today that the Ministry of Health, Labour and Welfare (MHLW) in Japan has granted marketing authorization for Xofigo[®] (radium-223 dichloride, radium-223) for the treatment of patients with castration-resistant prostate cancer and bone metastases. The product is already approved in more than 40 countries worldwide, including the U.S. and the countries of the European Union (EU).

“A majority of men living with advanced prostate cancer develop bone metastases, resulting in symptoms that can interfere with daily life, such as tiredness, weakness or difficulty doing normal activities, and decreased overall survival,” explained Dr. Hiroji Uemura, associate professor and department director of Urology and Renal Transplantation, Yokohama City University Medical Center. “Xofigo[®] has an anti-tumor effect that enables us to directly target bone metastases and potentially prolong survival, a critical treatment goal for patients with advancing disease. In addition, it is expected to delay the time to the first symptomatic skeletal event.”

Prostate cancer is the second most commonly diagnosed malignancy in men worldwide, and its incidence is rising in Japan. 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.

“We are pleased that Xofigo is now available in Japan, providing a new and innovative therapy with a proven clinical benefit to patients with advanced disease,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “Prostate cancer has a significant impact on men in Japan, and

this is an important step in our ongoing commitment to deliver therapies to patient's need.”

The approval 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=0.681 (95% CI 0.542-0.857), p=0.00096]. The second 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)]. Median time to first symptomatic skeletal event, a secondary endpoint in ALSYMPCA, was 15.6 months for radium-223 versus 9.8 months for placebo [HR= 0.658 (95% CI 0.522-0.830)].

The most common adverse events (occurring at a rate of 25% or greater, all grades) in patients receiving radium-223 in the ALSYMPCA trial were bone pain (patients treated with radium-223: 51.7%, patients in the placebo group: 63.5%), nausea (35.5%, 33.9%), anemia (31.2%, 30.6%), fatigue (26.5%, 25.9%), diarrhea (25.7%, 15.0%). The most common hematologic laboratory abnormalities were anemia (31.2%, 30.6%), neutropenia (5.0%, 1.0%), pancytopenia (2.0%, 0%), thrombocytopenia (4.2%, 0.3%) and lymphocytopenia (0.8%, 0.3%).

ALSYMPCA Trial Design

The ALSYMPCA trial was a Phase III, randomized, double-blind, placebo-controlled international study of Xofigo with best standard of care vs. placebo with best standard of care in symptomatic castration-resistant prostate cancer (CRPC) patients with bone metastases. Interim and updated analyses of the trial showed Xofigo significantly improved overall survival.

About Castration-Resistant Prostate Cancer (CRPC) and Bone Metastases

The stage of prostate cancer is one of the most important factors in determining treatment options and the outlook for recovery. If prostate cancer spreads, or metastasizes, beyond the prostate gland, it often first grows into nearby tissues or lymph nodes before spreading to the bones.

CRPC is an advanced form of prostate cancer. Approximately nine in 10 patients with advanced prostate cancer (90 percent) develop bone metastases, impacting survival and

quality of life. In fact, bone metastases lead to an increased risk of morbidity and death in patients with CRPC. Therefore, diagnosing and treating bone metastases at the earliest onset is critical for patients.

About Xofigo® (radium-223 dichloride)

Xofigo is an alpha particle-emitting therapeutic anti-tumor pharmaceutical. The active ingredient in Xofigo is the alpha particle-emitting isotope radium-223, which 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.

In countries of the EU, Xofigo is indicated for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. Radium-223 is also being studied in additional trials for men with prostate cancer as well as in Phase II studies for women with breast cancer.

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.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.com.

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