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Investor News

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Phase III trial of radium-223 dichloride in combination with abiraterone acetate and prednisone/prednisolone for patients with metastatic castration-resistant prostate cancer unblinded early

Decision follows a recommendation from an Independent Data Monitoring Committee

Leverkusen, November 30, 2017 – Bayer today announced that an Independent Data Monitoring Committee (IDMC) has recommended to unblind a Phase III trial of radium-223 dichloride (radium-223) in combination with abiraterone acetate and prednisone/prednisolone in prostate cancer. The IDMC recommendation is due to the observation of an imbalance of more fractures and deaths in the treatment arm investigating radium-223 in combination with abiraterone acetate and prednisone/prednisolone in patients with asymptomatic or mildly symptomatic chemotherapy-naïve metastatic castration-resistant prostate cancer (mCRPC). Bayer is unblinding the study per the IDMC's recommendation and will thoroughly analyze the findings and continue monitoring as per study protocol. Data from other types of studies in which this combination treatment was evaluated did not show new safety signals.

“Patient safety is our top priority. We are therefore unblinding the study to thoroughly analyze the data”, said Mike Devoy, Member of the Pharmaceuticals' Division Executive Committee and Chief Medical Officer at Bayer. “It is important to note that, based on available data from previous trials as well as real-world use, the benefit-risk profile of Xofigo in its approved indication remains favorable. We remain committed to further exploring the potential of radium-223 across multiple tumor types with significant unmet medical need, including prostate cancer.”

The trial evaluates the treatment of radium-223 in combination with abiraterone acetate and prednisone/prednisolone compared to placebo plus abiraterone acetate and prednisone/prednisolone in patients with asymptomatic or mildly symptomatic chemotherapy-naïve bone predominant metastatic castration-resistant prostate cancer (CRPC). The primary endpoint of the trial is symptomatic skeletal event-free survival

(SSE-FS). The trial completed enrollment in September 2016, therefore no patients in the combination arm are receiving radium-223 which is only administered for up to 6 doses (one dose every 4 weeks).

Bayer has informed relevant health authorities regarding the study unblinding as well as investigators of trials with radium-223 and is preparing the respective information for healthcare professionals. In addition, the company is in the process of gathering the detailed study findings and will update health authorities and healthcare professionals accordingly.

For further information, patients should contact their healthcare professionals.

Phase III Trial Design

The randomized double-blind, placebo-controlled Phase III trial ERA223 was designed to investigate whether providing radium-223 dichloride (radium-223) in combination with abiraterone acetate and prednisone/prednisolone will extend symptomatic skeletal event free survival (SSE-FS). The trial has enrolled 806 patients who were randomized in a 1:1 ratio to receive either study treatment of radium-223 dichloride for six cycles with abiraterone acetate plus prednisone / prednisolone or placebo for six cycles with abiraterone acetate plus prednisone/prednisolone and best supportive care. Patients in both arms were scheduled to receive treatment with abiraterone acetate plus prednisone/prednisolone until an on-study symptomatic skeletal event (SSE) occurred (or other withdrawal criteria were met). For further information about the study, please visit www.clinicaltrials.gov.

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 Radium-223 Dichloride

Radium-223 dichloride (radium-223) is a Targeted Alpha Therapy. It selectively targets bone, specifically areas of bone metastases, by forming complexes with the bone mineral hydroxyapatite. The high linear energy transfer of alpha particles 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, Radium-223 dichloride is indicated for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. The compound has already been approved in more than 50 countries worldwide, including the U.S., countries of the EU and Japan, under the brand name Xofigo[®]. 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 and patients with multiple myeloma.

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 2016, the Group employed around 99,600 people and had sales of EUR 34.9 billion. Capital expenditures amounted to EUR 2.2 billion, R&D expenses to EUR 4.4 billion. For more information, go to www.bayer.com.

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