



News Release

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Results of Phase III Study in Patients with Castration-Resistant Prostate Cancer and Symptomatic Bone Metastases:

Positive Phase III Data on Bayer's Investigational Drug Radium-223 Chloride Show Significant Increase in Overall Survival

- Data will be presented as part of Presidential Session featuring best and late-breaking abstracts at 2011 European Multidisciplinary Cancer Congress
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Wayne, NJ, September 23, 2011 – Bayer HealthCare Pharmaceuticals today announced that the investigational drug radium-223 chloride showed positive data in the Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **PRO**state **CAN**cer) trial. The study met its primary endpoint by significantly improving overall survival by 44% ($p=0.00185$, $HR=0.695$) in patients with castration-resistant prostate cancer (CRPC) and symptomatic bone metastases. All of the main secondary efficacy endpoints analyzed to date were met, including delay in skeletal-related events (SREs). These data will be presented during the Presidential Session at the 2011 European Multidisciplinary Cancer Congress in Stockholm, Sweden (Abstract No. 1LBA: Presidential Session I: Best and Late Breaking Abstracts, Saturday, September 24, 13.45 (CEST), Hall A1). The 2011 European Multidisciplinary Cancer Congress is the 16th congress of the European CanCer Organisation (ECCO), the 36th congress of the European Society for Medical Oncology (ESMO) and the 30th congress of European Society for Therapeutic Radiology and Oncology (ESTRO).

The data showed that patients who were treated with radium-223 chloride had the following outcomes:

- Median overall survival of 14 months compared to 11.2 months for the placebo group,
- Time to first SREs (13.6 months vs. 8.4 months, 64% improvement, $HR=0.610$, $p=0.00046$),
- Total alkaline phosphatase (ALP) normalization (33% vs. 1% of patients, $p<0.001$); and
- A 49% improvement in time to prostate-specific antigen (PSA) progression ($HR=0.671$, $p=0.00015$).

The most common non-hematologic adverse events (occurring in at least 15% of patients) included bone pain (43% vs. 58%), nausea (34% vs. 32%), diarrhea (22% vs. 13%), constipation (18% vs. 18%) and vomiting (17% vs. 13%); and the most common hematologic adverse events included anemia (27% vs. 27%) for patients receiving radium-223 chloride as compared to placebo. With respect to Grade 3 to 4 AEs, the most common events included bone pain (18% vs. 23%) for patients receiving radium-223 chloride as compared to placebo. Following a pre-planned interim analysis, the company agreed with the Independent Data Monitoring Committee's (IDMC) recommendation to stop the study and offer patients on the placebo arm treatment with radium-223 chloride.

“Radium-223 chloride is the first bone-targeted, alpha-emitting, radio-pharmaceutical to demonstrate a survival benefit in men with castration-resistant prostate cancer and symptomatic bone metastases,” said Dr. Oliver Sartor of Tulane Medical School, New Orleans, and an ALSYMPCA trial investigator.

Radium-223 chloride was recently granted Fast Track designation by the U.S. Food & Drug Administration (FDA). The Fast Track process is designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The company plans to file a New Drug Application with the FDA for radium-223 chloride in mid-2012.

ALSYMPCA Trial Design

The ALSYMPCA trial is a Phase III, randomized (2:1), double-blind, placebo-controlled international study of radium-223 chloride plus current standard of care compared with placebo plus current standard of care in patients with symptomatic CRPC that has spread to the bone. The primary endpoint of the study is overall survival. Secondary endpoints include time to occurrence of SREs, changes and time to progression in PSA and ALP, safety, and impact on quality of life measures.

ALSYMPCA enrolled 922 patients in more than 100 centers in 19 countries who have histologically or cytologically confirmed adenocarcinoma of the prostate, known hormone refractory disease, multiple skeletal metastases (≥ 2 hot spots) on bone scintigraphy, no intention to use cytotoxic chemotherapy within the next 6 months and either regular (not occasional) analgesic medication use for cancer related bone pain and treatment with EBRT for bone pain. ALSYMPCA was initiated by Algeta ASA (Oslo, Norway) in June 2008.

About Radium-223 Chloride

Radium-223 chloride is an investigational alpha-pharmaceutical (an alpha-emitting radio-pharmaceutical) in development for cancer patients with bone metastases. In September 2009, Bayer signed an agreement with Algeta for the development and commercialization of radium-223 chloride. Under the terms of the agreement, Bayer will develop, apply for global health authority approvals, and commercialize radium-223 chloride globally, while Algeta retains an option for up to 50/50 co-promotion and profit-sharing in the United States.

Radium-223 chloride is an investigational agent and is not approved by the FDA, the European Medicines Agency (EMA), or other health authorities.

About CRPC and Bone Metastases

Prostate cancer is the most common cancer among men in the United States and other developed countries (other than skin cancer). Approximately 15% of prostate cancer cases are considered regional or distant, which means that the cancer has spread beyond the prostate to nearby or distant areas of the body (metastasis).

CRPC is also known as hormone-refractory prostate cancer (HRPC). A majority of men with CRPC have radiological evidence of 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 and overall quality of life. Bone metastases secondary to prostate cancer typically target the lumbar spine, vertebrae and pelvis. In fact, bone metastases are the main cause of disability and death in patients with CRPC.

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals business of Bayer HealthCare LLC, a subsidiary of Bayer AG. Bayer HealthCare is one of the world's leading, innovative companies in the healthcare and medical products industry, and combines the activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. As a specialty pharmaceutical company, Bayer HealthCare

Pharmaceuticals provides products for Diagnostic Imaging, General Medicine, Hematology, Neurology, Oncology and Women's Healthcare. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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