Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

Not intended for U.S. and U.K. media

Results of pivotal Phase III study in patients with castration-resistant prostate cancer (CRPC) and bone metastases:

Updated Phase III Data Confirm Overall Survival Benefit with Bayer's Investigational Drug Alpharadin (Radium-223 Dichloride) in Men with Advanced Prostate Cancer that has Spread to the Bone

- Overall survival in radium-223 dichloride arm significantly increased by 44%, median overall survival benefit increased to 3.6 months
- Radium-223 dichloride led to a statistically significant delay in time to first skeletal related event (SRE)
- Updated survival results from ALSYMPCA trial presented as Late-Breaking Abstract in oral abstract session

---

LBA #4512

Leverkusen, Germany, June 4, 2012 – Bayer HealthCare today announced that updated data from the pivotal Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) trial for its investigational drug Alpharadin (radium-223 dichloride) confirm the overall survival benefit in men with castration-resistant prostate cancer (CRPC) and symptomatic bone metastases compared to the interim analysis from June 2011. The updated data showed that radium-223 dichloride improved overall survival by 44% (p=0.00007, HR=0.695), resulting in a 30.5% reduction in the risk of death compared to placebo. The median overall survival benefit with radium-223 dichloride was 2.8 months at the time of the interim analysis in June 2011 and 3.6 months in this updated analysis (14.9 months in patients given radium-223 dichloride vs. 11.3 months with placebo). These data will be presented as a late-breaking abstract in an oral abstract session on June 5, 2012 at the 48th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL (USA) (LBA No. 4512).

“Bone metastases are one of the main causes of disability and death in patients with castration-resistant prostate cancer, yet until now there has been little progress made towards developing therapies that target the cancer when it has spread to the bone,” said Dr. Chris Parker of The Royal Marsden NHS Foundation Trust, London, and The Institute of Cancer Research, London, and principal investigator of ALSYMPCA. “Radium-223 dichloride is the first therapy specifically addressing prostate cancer that has spread to the bone that has shown in a Phase III trial to significantly improve overall survival.”

In addition to improving overall survival, radium-223 dichloride led to a statistically significant delay in time to first skeletal-related event (SRE).

The overall safety and tolerability profile for radium-223 dichloride was consistent with previous study results. The most common hematologic adverse events included anemia (31% vs. 31%), neutropenia (5% vs. 1%) and thrombocytopenia (12% vs. 6%) for patients receiving radium-223 dichloride compared to placebo. With respect to Grade 3 and 4 adverse events, the most common events included anemia (13% vs. 13%), neutropenia (2% vs. 1%) and thrombocytopenia (6% vs. 2%). The most common non-hematologic adverse events included bone pain (50% vs. 62%), nausea (36% vs. 35%), diarrhea (25% vs. 15%), and vomiting (19% vs. 14%) for patients receiving radium-223 dichloride as compared to placebo. With respect to Grade 3 to 4 adverse events, the most common events included bone pain (21% vs. 26%).

“These updated ALSYMPCA data showing continued improvement in overall survival with Alpharadin (radium-223 dichloride) are very encouraging, because they bring us one step closer to providing additional hope for men who are fighting prostate cancer at its most aggressive stage,” said Kemal Malik, MD, Member of the Bayer HealthCare Executive Committee and Head of Global Development. “Radium-223 dichloride showcases Bayer’s commitment in developing innovative treatments for patients for whom there are limited options.”

Radium-223 dichloride was 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. Fast Track designation must be requested by the drug company and can be initiated at any time during the drug development process. Bayer plans to file radium-223 dichloride for CRPC with regulatory authorities based on the ALSYMPCA data in the second half of 2012. In terms of further development activities, Bayer intends to conduct

studies in earlier settings of prostate cancer, including combination studies with other agents, as well as undertaking exploratory studies in other tumors such as breast cancer and osteosarcoma.

ALSYMPCA Trial Design

The ALSYMPCA trial was a Phase III, randomized, double-blind, placebo-controlled international study of Alpharadin (radium-223 dichloride) plus best standard of care compared with placebo plus best standard of care in patients with symptomatic CRPC that has spread to the bone. The trial enrolled 921 patients in more than 100 centers in 19 countries who were docetaxel ineligible or intolerable or had failed prior docetaxel therapy. The study treatment consisted of up to six intravenous administrations of Radium-223 dichloride or placebo each separated by an interval of four weeks.

The primary endpoint of the study was overall survival. Secondary endpoints included time to occurrence of SREs, changes and time to progression in PSA and ALP, safety, and impact on quality of life measures.

ALSYMPCA was initiated by Algeta ASA (Oslo, Norway) in June 2008.

About CRPC and Bone Metastases

Prostate cancer is the most common cancer among men in developed countries (other than skin cancer). 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 radiological evidence of bone metastases. The five-year survival rate in patients with prostate cancer with bone metastases is three percent. 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 the main cause of disability and death in patients with CRPC.

About Alpharadin (Radium-223 Dichloride)

Alpharadin (radium-223 dichloride) is an investigational alpha-particle emitting pharmaceutical (a pharmaceutical containing an alpha-particle emitting nuclide) 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 dichloride. Under the terms of the agreement, Bayer will develop, apply for global health authority approvals, and commercialize radium-223 dichloride globally. In April 2012, Algeta announced that it has exercised its option to co-promote radium-223 dichloride for the treatment of cancer patients with bone metastases in the United States in accordance to their agreement with Bayer.

Radium-223 dichloride is an investigational agent and is not approved by the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), or other health authorities.

About Bayer HealthCare

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), 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 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Juergen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Dr. Olaf Weber (+49-214-30-33567)
Fabian Klingen (+49-214-30-35426)
Ute Menke (+49-214-30-33021)

Forward-Looking Statements

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.