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Investor News

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FDA Grants Fast Track Designation to Bayer's Investigational Compound Alpharadin™ for the Treatment of Castration Resistant Prostate Cancer in Patients with Bone Metastases

Leverkusen, August 23, 2011 – Bayer HealthCare announced today that its investigational compound Alpharadin™ (radium-223 chloride), which is exclusively licensed from Algeta ASA, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of castration-resistant (hormone refractory) prostate cancer in patients with bone metastases.

"Prostate cancer is a leading cause of death among men all over the world. There is a significant unmet need for patients suffering from the advanced stages of the disease, especially in patients whose cancer has spread to the bone," said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. "We are excited that Alpharadin has achieved this important milestone and recognize this fast track designation as an important step in the overall development of Alpharadin, particularly for those patients in need of treatment."

In June, Bayer announced that the Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) trial evaluating Alpharadin in patients with CRPC and symptomatic bone metastases met its primary endpoint by significantly improving overall survival. Based on a recommendation from the Independent Data Monitoring Committee (IDMC), following a pre-planned interim analysis, the study was stopped and patients on the placebo arm have been offered treatment with Alpharadin. The overall survival result was statistically significant (two-sided p-value = 0.0022, HR = 0.699, the median overall survival was 14.0 months for Alpharadin and 11.2 months for placebo).

The safety and tolerability of Alpharadin were consistent with previous Phase I and Phase II trial outcomes and did not show any new or unexpected changes in the safety profile of

Alpharadin. The complete results from the study will be presented at an upcoming scientific meeting.

Fast Track Designation in the United States

Fast Track is a process designed to facilitate the development, and expedite the review of drugs to treat serious diseases and fill an unmet medical need. Fast Track addresses a broad range of serious diseases. Fast Track designation must be requested by the drug company and can be initiated at any time during the drug development process. Once a drug receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients.

About Alpharadin™
Alpharadin™ (radium-223 chloride) is an investigational alpha-pharmaceutical (a pharmaceutical containing an alpha-particle emitting nuclide) in development for cancer patients with bone metastases. This compound mimics many of the behaviors of calcium in the bone.

In September 2009, Bayer signed an agreement with Algeta for the development and commercialization of Alpharadin. Under the terms of the agreement, Bayer will develop, apply for global health authority approvals, and commercialize Alpharadin globally, while Algeta retains an option for up to 50/50 co-promotion and profit-sharing in the United States.

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

Alpharadin is a registered trademark.

About CRPC and Bone Metastases
Prostate cancer is the most common cancer among men in Northern European countries and the United States. In 2008, an estimated 903,000 men had prostate cancer and 250,000 died from the disease worldwide.

Castration-resistant prostate cancer (CRPC) was formerly known as hormone-refractory prostate cancer (HRPC). Approximately 90 percent 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 bone pain, fracture and other complications that can significantly impair a man's health. In fact, bone metastases are the main cause of disability and death in patients with CRPC.

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 16.9 billion (2010), 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 and manufacture products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2010) and is represented in more than 100 countries. Find more information at www.bayerhealthcare.com.

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