Bayer

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Investor News

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

Positive Phase III Data on Bayer's Investigational Drug Alpharadin Show Significant Increase in Overall Survival

First presentation of full data as part of Presidential Session featuring best and late-breaking abstracts at 2011 European Multidisciplinary Cancer Congress

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Leverkusen, September 24, 2011 – Bayer HealthCare Pharmaceuticals today announced positive data on its investigational drug Alpharadin (radium-223 chloride) from the Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) 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 endpoints were met, including delay in time to first 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 24 September, 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 Alpharadin had the following outcome:

- A median overall survival of 14 months compared to 11.2 months for the placebo group,
- Median time to first SREs of 13.6 vs. 8.4 months (64% improvement, HR=0.610, p=0.00046),

- Total alkaline phosphatase (ALP) normalization in 33% of patients taking Alpharadin vs. 1% of patients on placebo ($p<0.001$); and
- A 49% improvement in time to prostate-specific antigen (PSA) progression (HR=0.671, p=0.00015).

The overall safety and tolerability profile for Alpharadin was consistent with previous study results. 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%). In respect to Grade 3 to 4 adverse events, the most common events included bone pain (18% vs. 23%).The trial was halted earlier this year following a pre-planned interim analysis to offer patients on the placebo arm treatment with Alpharadin.

“These data are significant because they demonstrate that Alpharadin can prolong life in patients with castration-resistant prostate cancer and bone metastases,” said Dr. Chris Parker of the Royal Marsden Hospital, London, and principal investigator of ALSYMPCA. “These results and previous study findings suggest that Alpharadin, a novel alpha-pharmaceutical, may provide a new standard of care for the treatment of castration-resistant prostate cancer patients with bone metastases.”

Alpharadin 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. Fast Track designation must be requested by the drug company and can be initiated at any time during the drug development process. The company plans to file Alpharadin with regulatory authorities in the U.S. and Europe based on these data in mid-2012.

ALSYMPCA Trial Design

The ALSYMPCA trial was a Phase III, randomized, double-blind, placebo-controlled international study of Alpharadin 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 922 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 6 intravenous administrations of Alpharadin or placebo each separated by an interval of 4 weeks.

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

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 to target areas of high bone turnover in and around bone metastases.

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 FDA, the European Medicines Agency (EMA), or other health authorities.

Alpharadin is a registered trademark.

About CRPC and Bone Metastases
Prostate cancer is the most common cancer among men in developed countries including the United Kingdom and the United States (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.

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. 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

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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