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Investor News

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Alpharadin Significantly Improves Overall Survival in Phase III Trial in Patients with Castration-Resistant Prostate Cancer That Has Spread to the Bone

- Trial Stopped Based on Positive Data from Pre-Planned Interim Analysis
- Patients on Placebo Arm will be Offered Treatment with Alpharadin

Leverkusen, June 6, 2011 – Bayer Healthcare today announced that the Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) trial evaluating Bayer's investigational compound Alpharadin (radium-223 chloride), which is exclusively licensed from Algeta ASA, in patients with castration-resistant prostate cancer (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 will be stopped and patients on the placebo arm will be 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 complete results from the study will be presented at an upcoming scientific meeting.

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.

"Around 90 percent of men with advanced prostate cancer have bone metastases, which are the main cause of disability and death in this disease", said Dr. Chris Parker, Institute of Cancer Research and Royal Marsden Hospital, and Principal Investigator for ALSYMPCA. "Advanced prostate cancer has a poor prognosis and treatment options are limited. Based on the observed survival benefit and its safety profile, Alpharadin may become an important treatment for patients with bone metastases from advanced prostate cancer."

“Prostate cancer is a leading cause of cancer-related death in men globally, and late-stage patients who have experienced bone metastases are in need of additional treatment options,” said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. “We are extremely encouraged by the overall survival benefit shown in this analysis and are hopeful about the potential of Alpharadin to fill a treatment need for men with advanced prostate cancer.”

The company is evaluating the filing strategy for Alpharadin based on the IDMC's recommendation to stop this study and will offer patients in the placebo arm treatment with Alpharadin.

ALSYMPCA Trial Design

The ALSYMPCA trial is a Phase III, randomized (2:1), double-blind, multi-dose, placebo-controlled international study of Alpharadin plus current standard of care compared with placebo plus current standard of care in patients with symptomatic castration-resistant/hormone-refractory prostate cancer that has spread to the bone. The primary endpoint of the study is overall survival. Secondary endpoints include time to occurrence of skeletal related events (SRE), changes and time to progression in prostate-specific antigen (PSA) tests and alkaline phosphatase (ALP) tests, safety and impact on quality of life and health economics. ALSYMPCA was initiated by Algeta ASA (Oslo, Norway) in June 2008. Enrollment in the trial was completed in January 2011 and 922 patients were randomized.

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 16.913 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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