Bayer

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

# Investor News

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## Bayer to Present New Data Evaluating Investigational Oncology Compounds at 2011 ECCO-ESMO Congress

- Full results of Phase III Alpharadin trial being presented in Presidential Session I: Best and Late Breaking Abstracts
  Phase II trial results evaluating Regorafenib in multiple tumor types

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**Leverkusen, September 13, 2011** – Bayer HealthCare Pharmaceuticals announced today that the company will present new data on several of its investigational compounds at the 2011 European Multidisciplinary Cancer Congress (ECCO-ESMO), September 23-27, 2011, in Stockholm, Sweden. These presentations, including the pivotal Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) data evaluating Alpharadin (radium-223 chloride) in patients with castration-resistant prostate cancer (CRPC), will highlight the potential of Bayer's growing oncology pipeline.

"We look forward to presenting the complete Phase III Alpharadin data for the first time following the positive results from the ALSYMPCA interim analysis released earlier this year," said Kemal Malik, MD, Head of Global Development and member of the Bayer HealthCare Executive Committee. "These data, along with other presentations from our oncology pipeline, serve to demonstrate Bayer's commitment to advancing the science of cancer and to developing innovative cancer therapies that can help people with cancer live longer."

Studies evaluating Bayer's investigational oncology compounds being presented at ECCO-ESMO include:

**Alpharadin (radium-223 chloride)**

- LATE BREAKING ABSTRACT: Overall Survival Benefit of Radium-223 Chloride (Alpharadin™) in the Treatment of Patients with Symptomatic Bone Metastases in

Castration-resistant Prostate Cancer (CRPC): a Phase III Randomized Trial (ALSYMPCA)
    - Presidential Session I: Best and Late Breaking Abstracts
    - Saturday, 24-Sept-2011, 14:35 (2:35pm) CEST, Hall A1

- Twenty-Four-Month Safety Data From Phase II Studies of Radium-223 Chloride, a First-in-class Alpha-pharmaceutical With a Highly Favorable Safety Profile for Patients With Castration-resistant Prostate Cancer (CRPC) and Bone Metastases
    - Abstract # 7008, Poster Discussion Session: Genitourinary Malignancies - Prostate Cancer
    - Monday, 26-Sept-2011, 11:00am-12:00pm CEST, Hall A8

**Regorafenib (BAY 73-4506)**

- Phase II Trial of the Oral Multikinase Inhibitor Regorafenib (BAY 73-4506) as First-line Therapy in Patients With Metastatic or Unresectable Renal Cell Carcinoma (RCC)
    - Abstract # 7141, Poster Session: Genitourinary Malignancies - Other
    - Sunday, 25-Sept-2011, 14:00 (2:00pm)-16:30 (4:30pm) CEST

- Phase II Safety Study of the Oral Multikinase Inhibitor Regorafenib (BAY 73-4506) as Second-line Therapy in Patients With Hepatocellular Carcinoma
    - Abstract # 6576, Poster Session: Gastrointestinal Malignancies - Non-colorectal Cancer
    - Monday, 26-Sept-2011, 9:30am-12:00pm CEST

- Phase I Study to Assess the Safety, Tolerability and Pharmacokinetics of the Mulitkinase Inihibitor Regorafenib (BAY 73-4506) in Japanese Patients with Advanced Solid Tumors
    - Abstract # 1236, Poster Session: Drug Development
    - Monday, 26 Sept-2011, 14:00 (2:00pm)-16:30 (4:30pm) CEST

**About Alpharadin and the ALSYMPCA trial**

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 June, Bayer announced that the Phase III ALSYMPCA (**AL**pharadin in **SYM**ptomatic **P**rostate **CA**ncer) trial evaluating Alpharadin 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 was stopped and patients on the placebo arm have been offered treatment with Alpharadin.

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 United States Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other Health Authorities.

Alpharadin is a registered trademark.

**About Regorafenib**

Regorafenib is an investigational oral multi-kinase inhibitor of angiogenic, stromal and oncogenic receptor tyrosine kinases (TK). Regorafenib inhibits angiogenic kinases like receptors for VEGF which play central roles in angiogenesis. It also inhibits various oncogenic kinases including RAF, RET as well as stromal kinases such as KIT and PDGF, thereby helping to stop the proliferation of cancer cells. Regorafenib has shown antitumor activity in preclinical studies by inhibiting tumor growth in multiple xenograft models via antiangiogenic and antiproliferative mechanisms. Based on these results, Regorafenib is currently being investigated in clinical trials for its potential to treat patients with various tumor types.

Regorafenib is an investigational agent and is not approved by the United States Food and Drug Administration (FDA), the European Medicines Agency (EMA) or other Health Authorities.

**About Oncology at Bayer**

Bayer is committed to advancing the science of cancer, and translating this science into therapies that can help people with cancer live longer. With several potential first- and best-in-class compounds in clinical development, Bayer's oncology portfolio demonstrates the Company's commitment to improving the lives of people living with cancer.

**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.


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**

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