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# Investor News

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## ESMO 2014 to Feature New Oncology Data from Across Bayer Franchise

- Positive Results of the Phase III CONCUR trial of regorafenib in Asian patients with metastatic colorectal cancer to be presented in Proffered Paper Session
- Includes data from studies evaluating regorafenib, sorafenib and radium Ra 223 dichloride across six tumor types

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**Leverkusen, Germany, September 24, 2014** – Bayer HealthCare announced today that data from its oncology portfolio, including Stivarga® (regorafenib) tablets, Nexavar® (sorafenib) tablets and Xofigo® (radium Ra 223 dichloride) injection, will be presented at the European Society for Medical Oncology (ESMO) 2014 Congress taking place September 26 – 30 in Madrid, Spain. These data include an oral presentation on the Phase III CONCUR trial evaluating the efficacy and safety of regorafenib in Asian patients with previously treated metastatic colorectal cancer (mCRC).

“Bayer’s presence at this global conference demonstrates our commitment and progress in exploring new treatment options for cancer patients around the world across various tumor types through both our robust portfolio and pipeline,” said Dr. Joerg Moeller, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

Notable studies evaluating Bayer's oncology products at ESMO 2014 are listed below.

**Regorafenib**

- *CONCUR: A randomized, placebo-controlled phase 3 study of regorafenib (REG) monotherapy in Asian patients with previously treated metastatic colorectal cancer (mCRC)*
    - Oral Presentation 500O, Proffered Paper Session: Gastrointestinal tumors, colorectal
    - Saturday, September 27, 10:20 – 10:35 AM (CET), Madrid Room

- *REBECCA: A large cohort study of Regorafenib (REG) in the real-life setting in patients (pts) previously treated for metastatic colorectal cancer (mCRC)*
    - Abstract 602P,  Poster Display Session: Gastrointestinal tumors, colorectal
    - Monday, September 29,  12:45 – 1:45 PM (CET), Poster Area
- *The Cost of Survival Gains in Metastatic Colorectal Cancer (mCRC) in Four European Countries*
    - Abstract 604P_PR, Poster Display Session: Gastrointestinal tumors, colorectal
    - Monday, September 29,  12:45 – 1:45 PM (CET), Poster Area
- *Adjuvant regorafenib (REG) in stage IV colorectal cancer (CRC) after curative treatment of liver metastases: a phase III randomized, placebo (PBO)-controlled trial (COAST)*
    - Abstract 611TiP, Poster Display Session: Gastrointestinal tumors, colorectal
    - Monday, September 29,  12:45 – 1:45 PM (CET), Poster Area
- *A prospective, observational trial to further assess safety and efficacy of regorafenib in patients with metastatic colorectal cancer (mCRC) in routine clinical practice (CORRELATE)*
    - Abstract 613TiP, Poster Display Session: Gastrointestinal tumors, colorectal
    - Monday, September 29,  12:45 – 1:45 PM (CET), Poster Area
- *Analysis of treatment patterns of patients with advanced gastrointestinal stromal tumors (GIST) in EU5*
    - Abstract 1427P, Poster Display Session: Sarcoma
    - Monday, September 29,  12:45 – 1:45 PM (CET), Poster Area

**Sorafenib**

- *Correlation of sorafenib exposure with safety and efficacy from pivotal clinical trials in hepatocellular carcinoma (HCC) and renal cell cancer (RCC)*
    - Abstract 485P, Poster Display Session: Developmental therapeutics
    - Saturday, September 27, 12:45 – 1:45 PM (CET), Poster Area
- *Health economic analysis of the randomized multicenter phase II trial SAKK 77/08: sorafenib with or without everolimus in patients with unresectable hepatocellular carcinoma (HCC)*
    - Abstract 1039P, Poster Display Session: Health economics
    - Sunday, September 28, 12:45 – 1:45 PM (CET), Poster Area
- *A phase III randomized, double-blind, trial comparing sorafenib plus capecitabine versus placebo plus capecitabine in the treatment of locally advanced or metastatic HER2-negative breast cancer (RESILIENCE)*

    - Oral Presentation LBA8, Proffered Paper Session: Breast cancer, metastatic
    - Sunday, September 28, 2:10 – 3:45 PM (CET), Madrid Room
- *Final analysis of overall survival per subgroups of HCC patients in the prospective, non-interventional INSIGHT study treated with sorafenib*
    - Abstract 728P, Poster Display Session: Gastrointestinal tumors, non-colorectal
    - Monday, September 29, 12:45 – 1:45 PM (CET), Poster Area
- *An international observational study to assess the use of sorafenib after transarterial chemoembolization (TACE) in patients with hepatocellular carcinoma (HCC): OPTIMIS*
    - Abstract 743TiP, Poster Display Session: Gastrointestinal tumors, non-colorectal
    - Monday, September 29, 12:45 – 1:45 PM (CET), Poster Area

**Radium Ra 223 Dichloride (radium-223)**

- *External-beam radiation therapy (EBRT) use and safety with radium-223 dichloride (Ra) in patients (pts) with castration-resistant prostate cancer (CRPC) and symptomatic bone metastases (mets) from the ALSYMPCA trial*
    - Abstract 768P, Poster Display Session: Genitourinary tumors, prostate
    - Saturday, September 27, 12:45 – 1:45 PM, Poster Area
- *1.5-year post-treatment follow-up of radium-223 dichloride (Ra-223) safety in patients (pts) with castration-resistant prostate cancer (CRPC) and symptomatic bone metastases from ALSYMPCA: characterization of hematologic safety profiles*
    - Abstract 769P, Poster Display Session: Genitourinary tumors, prostate
    - Saturday, September 27, 12:45 – 1:45 PM, Poster Area
- *Reasons for Patients (Pts) Discontinuing Study Treatment (Tx) in the Phase 3 ALSYMPCA Trial of Radium-223 Dichloride (Ra-223) in Castration-Resistant Prostate Cancer (CRPC) With Bone Metastases (Mets)*
    - Abstract 770P, Poster Display Session: Genitourinary tumors, prostate
    - Saturday, September 27, 12:45 – 1:45 PM, Poster Area
- *ERA 223 – a phase 3 trial of radium-223 dichloride (Ra-223) in combination with abiraterone acetate (AA) and prednisone in the treatment of asymptomatic or mildly symptomatic chemotherapy-naïve patients with bone-predominant metastatic castration-resistant prostate cancer (CRPC)*
    - Abstract 803TiP, Poster Display Session: Genitourinary tumors, prostate
    - Saturday, September 27, 12:45 – 1:45 PM, Poster Area

- *Safety of radium-223 dichloride (Ra) with docetaxel (D) in patients (pts) with bone metastases (mets) from castration-resistant prostate cancer (CRPC): a phase 1/2a clinical trial*
    - Abstract 765PD, Poster Discussion Session: Genitourinary tumors, prostate
    - Sunday, September 28, 1:00 – 2:00 PM, Granada Room

**About Regorafenib (Stivarga®)**

Regorafenib is an oral multi-kinase inhibitor that inhibits various kinases within the mechanisms involved in tumor growth and progression – angiogenesis, oncogenesis and the tumor microenvironment. In preclinical studies, regorafenib inhibits several angiogenic VEGF receptor tyrosine kinases that play a role in tumor neoangiogenesis (the growth of new blood vessels). In addition to VEGFR 1-3 it also inhibits various oncogenic and tumor microenvironment kinases including TIE-2, RAF-1, BRAF, BRAFV600, KIT, RET, PDGFR, and FGFR, which individually and collectively impact upon tumor growth, formation of a stromal microenvironment and disease progression.

Regorafenib is approved under the brand name Stivarga® in more than 60 countries worldwide, including the U.S., Europe and Japan for the treatment of metastatic colorectal cancer. The product is also approved in more than 40 countries, including the U.S., Europe and Japan, for the treatment of metastatic gastrointestinal stromal tumors (GIST).

Regorafenib is a compound developed by Bayer. In 2011, Bayer entered into an agreement with Onyx Pharmaceuticals, Inc., an Amgen subsidiary, under which Onyx receives a royalty on all global net sales of regorafenib in oncology.

**About Sorafenib (Nexavar®)**

Sorafenib, an oral anti-cancer therapy, is approved under the brand name Nexavar® in more than 100 countries worldwide. In Europe, Nexavar is approved for the treatment of hepatocellular carcinoma (HCC); for the treatment of patients with advanced renal cell carcinoma (RCC) who have failed prior interferon-alpha or interleukin-2 based therapy or are considered unsuitable for such therapy; and for progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma, refractory to radioactive iodine.

In preclinical studies, sorafenib has been shown to inhibit multiple kinases thought to be involved in both cell proliferation (growth) and angiogenesis (blood supply) - two

important processes that enable cancer growth. These kinases include Raf kinase, VEGFR-1, VEGFR-2, VEGFR-3, PDGFR-B, KIT, FLT-3 and RET.

Nexavar is co-developed by Onyx Pharmaceuticals, Inc., an Amgen subsidiary, and Bayer, except in Japan where Bayer manages all development. The companies co-promote Nexavar in the U.S. Outside of the U.S., excluding Japan, Bayer has exclusive marketing rights, and Bayer and Onyx share profits globally.

**About Radium-223 Dichloride (Xofigo®)**

Radium-223 dichloride (radium-223) is a therapeutic alpha particle-emitting pharmaceutical with an anti-tumor effect on bone metastases. Radium-223 mimics calcium and selectively targets bone, specifically areas of bone metastases, by forming complexes with the bone mineral hydroxyapatite. The high linear energy transfer of alpha emitters leads to a high frequency of double-strand DNA breaks in adjacent tumor cells, resulting in a potent cytotoxic effect. The alpha particle range from radium-223 is less than 100 micrometers, which minimizes damage to the surrounding normal tissue.

Radium-223 dichloride has been approved under the brand name Xofigo® in more than 40 countries worldwide, including the U.S. and the EU. In Europe, it is approved for the treatment of adults with CRPC, symptomatic bone metastases and no known visceral metastases.

**About Oncology at Bayer**

Bayer is committed to delivering *science for a better life* by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now includes three oncology products and several other compounds in various stages of clinical development. Together, these products reflect the company's approach to research, which prioritizes targets and pathways with the potential to impact the way that cancer is treated.

**About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of health care, agriculture and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 18.9 billion (2013), 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 56,000 employees (Dec 31, 2013) and is represented in more than 100 countries. More information is available at www.healthcare.bayer.com.

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