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Investor News

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American Society of Hematology 56th Annual Meeting and Exposition 2014:

Bayer to Present Latest Data on Its Hematology and Oncology Portfolio

- Three-year results from the Phase III SPINART study for octocog alfa (Kogenate[®] FS) in patients with hemophilia A
 - New data on damoctocog alfa pegol (BAY 94-9027) for the treatment of hemophilia A
 - Presentations on copanlisib and sorafenib in patients with different hematological cancers
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Leverkusen, Germany, December 1, 2014 – Bayer HealthCare will present latest data from its hematology and oncology portfolio at the American Society of Hematology (ASH) 56th Annual Meeting, December 6-9, 2014, in San Francisco, CA. The presentations will describe the results from a Phase III study with octocog alfa (approved for hemophilia A under the trade name of Kogenate[®] FS (Kogenate[®] Bayer in the EU)) as well as clinical and non-clinical results on damoctocog alfa pegol (BAY 94-9027) for hemophilia A therapy. Also, Phase II clinical trials results with sorafenib (approved for various indications relating to cancer of the liver, the kidney and the thyroid under the trade name Nexavar[®]) and copanlisib are presented for the treatment of different hematological cancers.

The presented data on Bayer's products include two oral presentations. One presentation will discuss the three-year findings from the Phase III SPINART study for antihemophilic treatment with octocog alfa. The SPINART study evaluated the secondary prophylaxis with octocog alfa on bleeding frequency and joint damage compared to episodic treatment in adults with severe hemophilia A. The other oral presentation will show the results of an independent investigator-sponsored randomized study of Dresden University and the Studienallianz Leukämie (SAL) with sorafenib in combination with standard chemotherapy for the treatment of acute myeloid leukemia.

The following studies evaluating Bayer's products will be presented at ASH 2014:

Hemophilia:

Octocog alfa (Kogenate® FS)

- *Associations Between Joint Damage and Quality of Life Among Patients with Severe Hemophilia A in the 3-Year SPINART Trial*
 - Abstract #200, Session: 901. Health Services and Outcomes Research – Non-Malignant Conditions: Bleeding and Clotting Disorders: Real World Outcomes, Oral Presentation
 - Sunday, December 7, 2014: 4:45 PM; South Building, Gateway Ballroom 104

- *Regional Differences in Patient-Reported Outcomes in a Study of Adult Prophylaxis vs On-Demand Treatment with Bayer's Sucrose-Formulated Recombinant Factor VIII: 3-Year Data from SPINART.*
 - Abstract #1518, Session: 322. Disorders of Coagulation or Fibrinolysis: Poster I
 - Saturday, December 6, 2014, 5:30 PM-7:30 PM; West Building, Level 1

- *Effect on Joint Health of Routine Prophylaxis With Bayer's Sucrose-Formulated Recombinant Factor VIII (rFVIII-FS) in Adolescents and Adults Previously Treated On Demand: MRI Analyses From the 3-Year SPINART Study*
 - Abstract #2854, Session: 322. Disorders of Coagulation or Fibrinolysis: Poster II
 - Sunday, December 7, 2014, 6:00 PM-8:00 PM; West Building, Level 1

Damoctocog alfa pegol (BAY 94-9027)

- *Bleeding Phenotype With Various BAY 94-9027 Dosing Regimens: Subanalyses From the PROTECT VIII Study*
 - Abstract #1526, Session: 322. Disorders of Coagulation or Fibrinolysis: Poster I
 - Saturday, December 6, 2014, 5:30 PM-7:30 PM; West Building, Level 1
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- *Reduced Polyethylene Glycol-Conjugated B-Domain-Deleted Factor VIII (PEG-BDD-FVIII) Clearance: Selective PEG Steric Modulation Without Affecting Potency*

- Abstract #1471, Session: 321. Blood Coagulation and Fibrinolytic Factors: Poster I
- Saturday, December 6, 2014, 5:30 PM-7:30 PM; West Building, Level 1
- *Site-Directed Pegylation of BDD FVIII (BAY 94-9027) Does Not Alter the Ability of the Molecule to Generate Thrombin, Activate Factor X or Become Inactivated By Activated Protein C*
 - Abstract #1492, Session: 322. Disorders of Coagulation or Fibrinolysis: Poster I
 - Saturday, December 6, 2014, 5:30 PM-7:30 PM; West Building, Level 1

Hematological Cancers:

Copanlisib

- *Phase 2A Study of Copanlisib, a Novel PI3K Inhibitor, in Patients with Indolent Lymphoma*
 - Abstract #1701, Session: 623. Lymphoma: Chemotherapy, excluding Pre-Clinical Models: Poster I
 - Saturday, December 6, 2014, 5:30 PM-7:30 PM; West Building, Level 1

Sorafenib

- *Sorafenib Versus Placebo in Addition to Standard Therapy in Younger Patients with Newly Diagnosed Acute Myeloid Leukemia: Results from 267 Patients Treated in the Randomized Placebo-Controlled SAL-Soramf Trial*
 - Abstract #6, Session: Plenary Scientific Session, Oral Presentation
 - Sunday, December 7, 2014: 3:45 PM, North Building, Hall D

About Octocog alfa (Kogenate® FS/Kogenate® Bayer)

Octocog alfa, human coagulation factor VIII or antihemophilic factor, is the active substance in Kogenate® FS (Kogenate® Bayer in Europe), which is approved in more than 90 countries worldwide. In most countries, Kogenate® FS is approved for the treatment and prevention of bleeding in adults and children with hemophilia A, an inherited bleeding disorder.

Patients with hemophilia A lack coagulation factor VIII, which causes blood clotting problems such as bleeding in the joints, muscles and internal organs. Kogenate® FS is used to correct the factor-VIII deficiency by replacing the missing factor VIII, giving temporary control of the bleeding disorder.

The human coagulation factor VIII in Kogenate[®] FS is not extracted from human blood but is produced by a method known as 'recombinant DNA technology'.

About Damoctocog alfa pegol (BAY 94-9027)

The investigational product damoctocog alfa pegol (BAY 94-9027) is a site-specific PEGylated recombinant Factor VIII (rFVIII). PEGylation of the clotting factor is intended to slow-down the clearance of Factor VIII in the body, thus extending its plasma half-life. BAY 94-9027 is currently in Phase III clinical development for the treatment and prophylaxis of bleeding in patients with hemophilia A.

About Copanlisib

Currently in clinical Phase II, the investigational agent copanlisib is a novel pan-class I inhibitor of phosphatidylinositol 3-kinase (PI3K) with a predominant activity against both PI3K- δ (delta) and PI3K- α (alpha) isoforms. Copanlisib has shown promising early clinical signals in Phase I and II studies in heavily pretreated patients with indolent and aggressive B cell lymphomas. The intravenous small molecule inhibitor is one of the five new promising drug candidates, which should be ready by 2015 for a decision on advancement to Phase III.

About Sorafenib

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 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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