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105th Annual Meeting American Association for Cancer Research

Bayer to Present New Data on Advancing Oncology Portfolio

New Preclinical and Early Clinical Data Evaluating Innovative Compounds in Drug Development

Leverkusen, Germany, April 4, 2014 – Bayer HealthCare (Bayer) will present latest preclinical and clinical data on promising early-stage compounds with new mechanism of action at the American Association for Cancer Research (AACR) 105th Annual Meeting, April 5-9, 2014, in San Diego, CA.

"Bayer's presence at AACR this year reflects both our progress and our commitment to advancing the research and development of innovative treatments for tumor types with a high medical need," said Dr. Karl Ziegelbauer, Head of Therapeutic Research Group Oncology/Gynecological Therapy at Bayer HealthCare. "Cancer is a complex and heterogeneous disease. Being able to understand the molecular mechanisms driving different types of cancer will allow us to identify and develop novel targeted approaches to better treat this devastating disease."

Bayer will present new preclinical data, for example on three investigational agents currently in preclinical or Phase I clinical development targeting fibroblast growth factor receptors (FGFRs) whose increased expression is tied to tumor growth, angiogenesis, and chemoresistance. The agents include: a selective small molecule panFGFR1-3 kinase inhibitor (BAY 1163877); an anti-FGFR2 monoclonal antibody (BAY 1179470), as well as an FGFR2 antibody-drug conjugate (ADC). FGFR2-ADC carries a microtubule-disrupting agent, based on a technology licensed from Seattle Genetics, Inc. Through collaboration with the U.S.-based company, Bayer is also developing another ADC targeting tumors expressing C4.4a, a tumor-specific and metastases-associated tumor

antigen. Preclinical evidence of anti-tumor efficacy of C4.4a-ADC as investigational agent for lung cancer patients will be presented.

Preventing the binding of bromodomain and extra-terminal (BET) family proteins to chromatin is a promising novel therapeutic approach in the fight against cancer. For the first time, Bayer will present data on a new class of benzodiazepine BET-inhibitors with improved oral bioavailability. Selective inhibition of positive transcription elongation factor b (P-TEFb) may add a new key mechanism of action to current cancer therapies via the suppression of anti-apoptotic signals. Bayer is working on a class of selective P-TEFb/CDK9-inhibitors, originally licensed from Lead Discovery Center GmbH and first preclinical data will be shown at AACR.

Clinical Phase-I-results in patients with advanced stage small cell lung or ovarian cancer will be presented on the oral pan-CDK inhibitor Roniciclib (BAY 1000394). The anti-tumor agent, currently in Phase I/II testing, targets cyclin-dependent kinases (CDK) that are involved in crucial cellular functions such as tumor cell proliferation and survival signaling. New preclinical data are presented on two other Phase I investigational agents: BAY 1125976, a selective allosteric AKT1/2 inhibitor, and BAY 1082439, a novel phosphatidylinositol-3-phosphate (PI3K) inhibitor, which was tested in combination with radium-223 in a preclinical model of bone metastases.

Bayer also continues to broaden its network of collaborations with external academic and biotech partners in the area of oncology. Emerging data from joint projects will also be presented at AACR. The focus of Bayer's alliance with OncoMed Pharmaceuticals, Inc. is cancer stem cell research with the goal to develop small molecules as well as protein therapeutics targeting the Wnt signaling pathway. OncoMed will present preclinical and biomarker data on both their Frizzled/Wnt pathway antagonist FZD8-Fc (OMP-54F28) and anti-Frizzled/Wnt pathway antagonist Vantictumab (OMP-18R5). Phase I clinical trials with these agents are currently ongoing.

Another collaborative project of Bayer highlighted at AACR 2014 in San Diego is OncoTrack, which comprises an international consortium of about 100 scientists managed by Bayer and the Max Planck Institute for Molecular Genetics. The OncoTrack project which is funded by a unique public-private partnership between the pharmaceutical industry and the European Union, the so-called Innovative Medicines Initiative (IMI), focuses on developing novel genomic cancer diagnostics. The oral and

two poster presentations will evaluate data on recent advances in patient-tumor-derived mouse models and 3D cell cultures.

With a total of four oral and 22 poster presentations, Bayer has steadily increased its AACR presence over the last years.

The following list includes the AACR presentations to the previously mentioned Bayer pipeline studies and projects:

Oral Presentations

- <u>Charlotte Kopitz</u> (Bayer HealthCare): In vitro and in vivo characterization of a novel
 anti-fibroblast growth factor receptor (FGFR2) antibody for the treatment of
 gastric cancer
 - Drug Development Track: Special Session: New Drugs on the Horizon 2
 - o Sunday, April 6, 3:15 p.m.-3:40 p.m., Room 29, San Diego Convention Center
- <u>Jens Hoffmann</u> (Experimental Pharmacology and Oncology Berlin-Buch GmbH):
 Generation of drug response data from 57 new patient derived colon cancer
 xenografts and 3D cell cultures for systematic correlation with tumor biology within
 the **OncoTrack** project
 - Minisymposia: Tumor Biology 26: Innovations in Modeling Cancer in Mice;
 Presentation# 2978
 - o Monday, April 7, 4:35 p.m.-4:50 p.m., Room 30 A-C, San Diego Convention Center
- <u>Christoph Schatz</u> (Bayer HealthCare): Pharmacodynamic and stratification biomarker for the **anti-FGFR2 antibody (BAY1179470)** and the **FGFR2-ADC**
 - Minisymposia: Experimental and Molecular Therapeutics 39: Novel Biologics as Targeted Cancer Therapy; Presentation# 4766
 - o Tuesday, April 8, 3:20 p.m.-3:35 p.m., Room 5, San Diego Convention Center
- <u>Hilmar Weinmann</u> (Bayer HealthCare): New benzoazepine **BET-inhibitors** with improved oral bioavailability
 - Minisymposia: Chemistry 9: Small Molecule Design and Optimization;
 Presentation# 4749
 - Tuesday, April 8, 4:20 p.m.-4:35 p.m., Room 28 A-C, San Diego Convention Center

Selected Poster Presentations

- Pharmacokinetic and pharmacodynamics (PK/PD) modeling of preclinical data of a novel anti-fibroblast growth factor receptor (FGFR) 2 antibody (BAY 1179470) to guide dosing in phase I
 - Poster Session: Immunology 2: Therapeutic Antibodies; Presentation# 672
 - Sunday, April 6, 1:00 p.m.-5:00 p.m., San Diego Convention Center (Hall A-E),
 Poster Section 28, Poster# 29
- Preclinical profile of BAY 1163877 a selective pan-FGFR inhibitor in phase I clinical trial
 - Poster Session: Experimental and Molecular Therapeutics 12: Kinase Inhibitors 2;
 Presentation# 1739
 - Monday, April 7, 8:00 a.m.-12:00 p.m., San Diego Convention Center (Hall A-E),
 Poster Section 31, Poster# 12
- A phase I study with the oral pan-CDK inhibitor BAY 1000394 in patients with advanced stage small cell lung or ovarian cancer
 - Poster Session: Clinical Trials: Early Phase Clinical Trials 1: Phase I;
 Presentation# CT209
 - Monday, April 7, 8:00 a.m.-12:00 p.m., San Diego Convention Center (Hall A-E),
 Poster Section 38, Poster# 9
- BAY 1125976 is a selective allosteric AKT1/2 inhibitor with high efficacy in AKT1mutated cancers
 - Poster Session: Experimental and Molecular Therapeutics 25: Cellular and Molecular Pharmacology; Presentation# 3685
 - Tuesday, April 8, 8:00 a.m.-12:00 p.m., San Diego Convention Center (Hall A-E),
 Poster Section 30, Poster# 12
- Combination of **PI3K inhibitor** BAY 1082439 with **radium-223** is a promising treatment of cancer with bone metastases
 - Poster Session: Tumor Biology 40: Therapeutic Approaches for Metastatic Tumors; Presentation# 4022
 - Tuesday, April 8, 1:00 p.m.-5:00 p.m., San Diego Convention Center (Hall A-E),
 Poster Section 7, Poster# 1

- **FGFR2-ADC** potently and selectively inhibits growth of gastric and breast cancer xenograft models.
 - Poster Session: Experimental and Molecular Therapeutics 31: Biologic Therapy 3;
 Presentation# 4491
 - Tuesday Apr 8, 1:00 PM 5:00 PM, San Diego Convention Center (Hall A-E),
 Poster Section 29, Poster# 1
- PTEFb-BAY1, a highly selective, potent and orally available inhibitor of PTEFb/CDK9, shows convincing anti-tumor activity
 - Poster Session: Experimental and Molecular Therapeutics 32: Cell Cycle and PI3K/AKT Inhibitors: Presentation# 4538
 - Tuesday, April 8, 1:00 p.m.-5:00 p.m., San Diego Convention Center (Hall A-E),
 Poster Section 30, Poster# 24
- Preclinical anti-tumor efficacy of an anti-C4.4a (LYPD3) antibody drug conjugate for the treatment of lung cancer including squamous cell carcinoma
 - Poster Session: Experimental and Molecular Therapeutics 40: Biologic Therapy 4;
 Presentation# 5445
 - Wednesday, April 9, 8:00 a.m.-12:00 p.m., San Diego Convention Center (Hall A-E), Poster Section 30, Poster# 21

Further details on additional oral and poster presentations can be found at the AACR website (www.aacr.org).

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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Forward-Looking Statements

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