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## Investor News

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American Association for Cancer Research (AACR) 108th Annual Meeting:

### **Bayer to Showcase Data on Growing Oncology Pipeline at AACR 2017**

- Results from pivotal Phase II trial CHRONOS-1 of investigational PI3K inhibitor copanlisib selected for oral presentation at congress' Clinical Trial Session
  - Early research findings from across the company's oncology development portfolio will also be presented
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**Abstracts:** Oral presentations 983; 984; CT149; Poster presentations 154 / 21; 160 / 27; 836 / 14; 1079 / 2; 3091 / 2; 3738 / 23; CT094 / 12; 5036 / 11; 5199 / 17; 5200 / 18; 5202 / 20; 5859 / 22

**Leverkusen, Germany, March 22, 2017** – Bayer will present the latest research from its growing oncology portfolio at the American Association for Cancer Research (AACR) 2017 Annual Meeting, taking place on April 1-5 in Washington, D.C., USA. These presentations reflect the company's diverse pipeline, with findings from clinical and preclinical studies in a variety of hematologic and solid cancers.

Among these data are clinical results from the CHRONOS-1 trial evaluating copanlisib in patients with relapsed or refractory indolent non-Hodgkin's lymphoma (iNHL), which will be presented for the first time as part of the congress' Clinical Trial Session. Also scheduled are a series of preclinical data presentations including a number of small molecules, such as Bayer's oral multikinase inhibitor regorafenib, the pan-fibroblast growth factor receptor (FGFR) inhibitor BAY 1163877, the positive transcription elongation factor (PTEFb) inhibitor BAY 1251152 and the ataxia telangiectasia rad3-related protein (ATR) inhibitor BAY 1895344. In addition, data on Bayer's antibody-drug conjugate (ADC) platform will be presented, including the C4.4a-ADC BAY1129980 and the FGFR2-ADC BAY 1187982, as well as data on three new chemical entities from Bayer's emerging Targeted Thorium Conjugate (TTC) platform, which carry an alpha-

particles emitting payload as a toxophore. Preclinical results of radium-223 dichloride complement the targeted alpha therapy data being presented.

The total of five oral and 26 poster presentations underscore Bayer's comprehensive approach to research and development for advancing oncology pipeline projects that have the potential to be first-in-class in their category. This approach allows the company to explore a variety of agents with different mechanisms of action, develop new delivery platforms and drive toward the goal of offering innovative treatment approaches for patients battling cancers with a high medical need.

The following list comprises a selection of presentations on Bayer pipeline projects presented at AACR 2017:

### Oral Presentations

- *Identification of potent, highly selective and orally available **ATR inhibitor** BAY 1895344 with favorable PK properties and promising efficacy in monotherapy and combination in preclinical tumor models*
  - Oral presentation 983, Session: MS.CH01.01 - Novel Therapeutic Targets, Molecules, and Approaches for the Treatment of Cancer
  - Sunday, April 2, 4:20 pm – 4:35 pm (ET), Room 201, Level 2
  
- *Identification of potent and highly selective **PTEFb inhibitor** BAY 1251152 for the treatment of cancer: from p.o. to i.v. application via scaffold hops*
  - Oral presentation 984, Session: MS.CH01.01 - Novel Therapeutic Targets, Molecules, and Approaches for the Treatment of Cancer
  - Sunday, April 2, 4:35 pm – 4:50 pm (ET), Room 201, Level 2
  
- **Copanlisib** in patients with relapsed or refractory indolent B-cell lymphoma: *Primary results of the pivotal CHRONOS-1 study*
  - Oral presentation CT149, Clinical Trial Session: CTMSO3 – Novel Agent and Intervention Clinical Trials
  - Tuesday, April 4, 3:05 pm – 3:20 pm (ET), Hall D-E, Level 2

## Selected Poster Presentations

- *The phosphatidylinositol-3-kinase (PI3K) inhibitor **copanlisib** is active in preclinical models of B-cell lymphomas as single agent and in combination with conventional and targeted agents including venetoclax and palbociclib*
  - Poster 154 / 21, Session: PO.ET06.08 - Targeting the PI3K Pathway
  - Sunday, April 2, 1 pm – 5 pm (ET), Section 6
- *High target binding affinity with long lasting cellular target engagement and high dose intermittent schedule of PI3K inhibitor **copanlisib** contribute to the potent anti-tumor activity and good safety profile*
  - Poster 160 / 27, Session: PO.ET06.08 - Targeting the PI3K Pathway
  - Sunday, April 2, 1 pm – 5 pm (ET), Section 6
- ***ATR inhibitor** BAY 1895344 shows potent anti-tumor efficacy in monotherapy and strong combination potential with the targeted alpha therapy Radium-223 dichloride in preclinical tumor models*
  - Poster 836 / 14, Session PO.TB09.01 - Cellular Responses to Ionizing Radiation
  - Sunday, April 2, 1 pm – 5 pm (ET), Section 39
- *Preclinical activity of the **FGFR inhibitor** BAY 1163877 alone or in combination with antihormonal therapy in breast cancer*
  - Poster 1079 / 2, Session: PO.ET01.03 - Combination Therapy 1
  - Monday, April 3, 8 am – 12 pm (ET), Section 2
- *Response of C4.4A-positive patient-derived xenograft models of ESCC, HNSCC and bladder cancer to BAY1129980, a **C4.4A-targeted antibody drug conjugate***
  - Poster 3091 / 2, Session: PO.ET01.02 - Drug Delivery Technology and Antibody Technology
  - Tuesday, April 4, 8 am – 12 pm (ET), Section 4
- *Use of tumor mRNA expression for patient selection in a phase I study of the **pan-fibroblast growth factor receptor inhibitor** BAY 1163877*
  - Poster 3738 / 23, Session: PO.CL01.04 - Clinical Laboratory and Imaging Correlates
  - Tuesday, April 4, 8 am – 12 pm (ET), Section 29

- *Phase I study of fibroblast growth factor receptor 2 antibody-drug conjugate (FGFR2-ADC) BAY 1187982 in patients with advanced cancer*
  - Poster CT094 / 12, Session PO.CT03 - Phase I Clinical Trials
  - Tuesday, April 4, 8 am – 12 pm (ET), Section 33
  
- *Correlation of preclinical antitumor activity of **regorafenib** in CRC-PDX xenografts with gene expression and clinical parameters of the primary tumor*
  - Poster 5036 / 11, Session: PO.ET05.02 - Anticancer Precision Clinical Pharmacology
  - Wednesday, April 5, 8 am – 12 pm (ET), Section 1
  
- *Preclinical activity of the **FGFR2-targeted thorium-227 conjugate** in preclinical models of colorectal, gastric and triple-negative breast cancer*
  - Poster 5199 / 17, Session PO.ET09.01 - Preclinical Radiotherapeutics
  - Wednesday, April 5, 8 am – 12 pm (ET), Section 7
  
- *Preclinical pharmacology of the **PSMA targeted thorium-227 conjugate PSMA-TTC: A novel targeted alpha therapeutic for the treatment of prostate cancer***
  - Poster 5200 / 18, Session PO.ET09.01 - Preclinical Radiotherapeutics
  - Wednesday, April 5, 8 am – 12 pm (ET), Section 7
  
- *Additive benefits of **radium-223 dichloride** and bortezomib combination in a syngeneic 5TGM1 multiple myeloma mouse model*
  - Poster 5202 / 20, Session: PO.ET09.01 - Preclinical Radiotherapeutics
  - Wednesday, April 5, 8 am – 12 pm (ET), Section 7
  
- ***HER2-targeted thorium-227 conjugate (HER2-TTC): Efficacy in preclinical models of trastuzumab and T-DM1 resistance***
  - Poster 5859 / 22, Session PO.TB09.02 - Radioprotectors, Radiosensitizers, and Radiation Resistance
  - Wednesday, April 5, 8 am – 12 pm (ET), Section 41

### **About Copanlisib**

Copanlisib is a novel pan-class I PI3K inhibitor being developed by Bayer with predominant inhibitory activity against PI3K-  $\alpha$  and PI3K-  $\delta$  isoforms. The PI3K pathway is involved in cell growth, survival and metabolism, and its dysregulation plays an important role in NHL. Copanlisib is administered as a 1-hour infusion on an intermittent weekly basis (3 weeks on/1 week off).

Copanlisib has shown promising early clinical activity in Phase I and Phase II studies in heavily pretreated patients with recurrent indolent and aggressive NHL. The broad clinical development program also includes Phase III studies in indolent NHL patients who have relapsed or are refractory to prior therapies. Information about these trials can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and [www.chronotrials.com](http://www.chronotrials.com).

Copanlisib is not approved by the U.S. Food and Drug Administration, the European Medicines Agency or any other health authority.

### **About Regorafenib (Stivarga®)**

Regorafenib is an oral multikinase inhibitor that potently blocks protein kinases involved in tumor angiogenesis (VEGFR1, -2, -3, TIE2), oncogenesis (KIT, RET, RAF-1, BRAF), metastasis (VEGFR3, PDGFR, FGFR) and tumor immunity (CSF1R).

Regorafenib is approved under the brand name Stivarga® in more than 90 countries worldwide, including the U.S., countries of the EU and Japan for the treatment of metastatic colorectal cancer. The product is also approved in over 80 countries, including the U.S., countries of the EU and Japan, for the treatment of metastatic gastrointestinal stromal tumors (GIST). In the EU, Stivarga is indicated for the treatment of adult patients with mCRC who have been previously treated with, or are not considered candidates for, available therapies including fluoropyrimidine-based chemotherapy, an anti-VEGF therapy and an anti-EGFR therapy, as well as for the treatment of adult patients with unresectable or metastatic GIST who progressed on or are intolerant to prior treatment with imatinib and sunitinib.

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

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

Radium-223 dichloride (radium-223) is an alpha particle-emitting therapeutic anti-tumor pharmaceutical. It 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 50 countries worldwide, including the U.S., countries of the EU and Japan. In countries of the EU, it is approved for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. Radium-223 is also being studied in additional trials for men with prostate cancer as well as in Phase II studies for women with breast cancer and patients with multiple myeloma.

### **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 includes three marketed 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.

### **Bayer: Science For A Better Life**

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to [www.bayer.com](http://www.bayer.com).

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**Forward-Looking Statements**

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