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## News Release

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American Society of Clinical Oncology (ASCO) 54<sup>th</sup> Annual Meeting:

### **Bayer highlights latest oncology research at ASCO 2018**

Clinical research to be presented from Bayer's growing oncology portfolio, including radium-223 dichloride, sorafenib, regorafenib, copanlisib and other pipeline compounds

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**Abstracts:** *Oral presentations:* 5008, 11500, 4502, 11504, 11505, 2507; *Poster presentations:* 5022, 1065, 5024, 5057, 5050, 5029, 4018, 6081, 4080, 4082, 3510, 3532, 11537, 2047, 8579, 7570, 1036, TPS5093, 4513, 5571, TPS2607

**Berlin, May 17, 2018** – Bayer announced today that the latest research across its growing oncology portfolio will be presented at the 54<sup>th</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO), taking place June 1-5 in Chicago, Illinois (USA).

The data being presented at ASCO span data on approved therapies as well as new research from Bayer's early and late-stage oncology pipeline compounds. In line with the theme of this year's meeting, "Delivering Discoveries: Expanding the Reach of Precision Medicine," the company's next wave of innovation includes larotrectinib, an investigational compound jointly developed by Bayer and Loxo Oncology against (Tropomyosin Receptor Kinase) TRK fusion cancer, a cancer driven by a specific genetic alteration. The New Drug Application in the U.S. was recently submitted to the U.S. Food and Drug Administration and a submission in the EU is planned later this year.

At ASCO 2018, results from a randomized Phase II study investigating three dosing regimens of radium-223 dichloride in bone metastatic castration-resistant prostate cancer (mCRPC) and a Phase III trial of sorafenib in desmoid tumors, sponsored by the National Cancer Institute, will be highlighted in oral presentations. Poster presentations of note include the final analysis from the global OPTIMIS study of outcomes in patients with hepatocellular carcinoma treated with transarterial chemoembolization (TACE), safety and tolerability data of radium-223 dichloride in combination with enzalutamide in patients with

mCRPC, and a subgroup analyses of diabetic patients from the Phase II CHRONOS-1 study of copanlisib in patients with relapsed or refractory indolent B-cell lymphoma.

Notable studies from Bayer's portfolio and pipeline therapies being featured at ASCO 2018 include the following:

### **Radium-223 dichloride (radium-223)**

- *A randomized phase 2 study investigating 3 dosing regimens of radium-223 dichloride in bone metastatic castration-resistant prostate cancer (mCRPC)*  
Abstract 5008, Oral Abstract Session: Genitourinary (Prostate) Cancer, Date: Monday, June 4, Time: 5:24 PM – 5:36 PM, Location: Hall D1
- *Radium-223 re-treatment in an international, open-label, phase 1/2 Study in patients with castration-resistant prostate cancer and bone metastases: 2-year follow-up*  
Abstract 5022, Poster Session: Genitourinary (Prostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A
- *Phase II study of Ra-223 combined with hormonal therapy and denosumab for treatment of hormone receptor-positive breast cancer with bone-dominant metastasis [investigator-initiated research; IIR]*  
Abstract 1065, Poster Session: Breast Cancer – Metastatic, Date: Saturday, June 2, Time: 8:00 AM – 11:30 AM, Location: Hall A
- *Radium-223: Disease response and fracture assessment by whole body diffusion-weighted MRI (WB-DWMRI) in metastatic castration resistant prostate cancer (mCRPC) [IIR]*  
Abstract 5024, Poster Session: Genitourinary (Prostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A
- *Safety data from a phase II randomized trial of radium-223 dichloride (Ra-223) plus enzalutamide (Enza) vs. Enza alone in men with metastatic castration refractory prostate cancer (mCRPC) [IIR]*  
Abstract 5057, Poster Session: Genitourinary (Prostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A
- *Phase II safety and tolerability study of Radium-223 (R223) in combination with enzalutamide (ENZA) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC): CTrial-IE (ICORG)13-21 [IIR]*

Abstract 5050, Poster Session: Genitourinary (Prostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A

- *Genomic and phenotypic evidence for prostate cancer osteomimicry in circulating tumor cells from men with metastatic castration resistant prostate cancer (mCRPC) treated with radium-223 [IIR]*

Abstract 5029, Poster Session: Genitourinary (Prostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A

## **Sorafenib**

- *Phase III, randomized, double blind, placebo-controlled trial of sorafenib in desmoid tumors (Alliance A091105) [IIR]*

Abstract 11500, Oral Abstract Session: Sarcoma, Date: Monday, June 4, Time: 8:00 AM – 8:12 AM, Location: S100a

- *A randomized, open label, multicenter phase 2 study, to evaluate the efficacy of sorafenib (So) in patients (pts) with metastatic renal cell carcinoma (mRCC) after a radical resection of the metastases: RESORT trial [IIR]*

Abstract 4502, Oral Abstract Session: Genitourinary (Nonprostate) Cancer, Date: Sunday, June 3, Time: 8:12 AM – 8:24 AM, Location: Arie Crown Theater

- Outcomes of patients (pts) with hepatocellular carcinoma (HCC) treated with transarterial chemoembolization (TACE): Global OPTIMIS final analysis

Abstract 4018, Poster Discussion Session: Gastrointestinal (Noncolorectal) Cancer, Date: Sunday, June 3, Time: 4:00 PM – 6:00 PM, Location: Hall D2

- Second interim analysis of RIFTOS MKI, a global non-interventional study assessing the use of multikinase inhibitors (MKIs) in the treatment of patients with asymptomatic radioactive iodine-refractory differentiated thyroid cancer (RAI-R DTC)

Abstract 6081, Poster Session: Head and Neck Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A

- *Phase II trial of sorafenib plus doxorubicin (SD) In patients (Pts) with advanced hepatocellular carcinoma (HCC) whose disease has progressed (POD) on sorafenib (S) [IIR]*

Abstract 4080, Poster Session: Gastrointestinal (Noncolorectal) Cancer, Date: Sunday, June 3, Time: 8:00 AM – 11:30 AM, Location: Hall A

## Regorafenib

- *Multi institutional phase II trial of single agent regorafenib in refractory advanced biliary cancers [IIR]*  
Abstract 4082, Poster Session: Gastrointestinal (Noncolorectal) Cancer, Date: Sunday, June 3, Time: 8:00 AM – 11:30 AM, Location: Hall A
- *REVERCE: Randomized phase II study of regorafenib followed by cetuximab versus the reverse sequence for metastatic colorectal cancer patients previously treated with fluoropyrimidine, oxaliplatin, and irinotecan – Biomarker analysis [IIR]*  
Abstract 3510, Poster Session: Gastrointestinal (Colorectal) Cancer, Date: Sunday, June 3, Time: 8:00 AM – 11:30 AM, Location: Hall A
- *High levels of cell-free DNA (cfDNA) at baseline (BL) and increase of at least one mutation at day 14 (D14) as independent prognostic biomarkers for patients (pts) with advanced colorectal cancer (aCRC) under regorafenib [IIR]*  
Abstract 3532, Poster Session: Gastrointestinal (Colorectal) Cancer, Date: Sunday, June 3, Time: 8:00 AM – 11:30 AM, Location: Hall A
- *Phase II trial of continuous dosing of regorafenib in patients with metastatic or recurrent gastrointestinal stromal tumors (GISTs) after failure of imatinib and sunitinib [IIR]*  
Abstract 11537, Poster Session: Sarcoma, Date: Saturday, June 2, Time: 8:00 AM – 11:30 AM, Location: Hall A
- *Results of randomized, placebo (PL)-controlled phase II study evaluating efficacy and safety of regorafenib (REG) in patients (pts) with metastatic osteosarcoma (metOS), on behalf of the French Sarcoma Group (FSG) and Unicancer [IIR]*  
Abstract 11504, Oral Abstract Session: Sarcoma, Date: Monday, June 4, Time: 9:12 AM – 9:24 AM, Location: S100a
- *A randomized, double-blind, placebo-controlled, phase II study of regorafenib vs placebo in advanced/metastatic, treatment-refractory liposarcoma: results from the SARC024 study [IIR]*  
Abstract 11505, Oral Abstract Session: Sarcoma, Date: Monday, June 4, Time: 9:24 AM - 9:36 AM, Location: S100a
- *Updated results of REGOMA: A randomized, multicenter, controlled open-label phase II clinical trial evaluating regorafenib in relapsed glioblastoma (GBM) patients (PTS) [IIR]*  
Abstract 2047, Poster Session: Central Nervous System Tumors, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A

- *A phase II study of regorafenib in patients with thymic epithelial tumors previously treated with chemotherapy [IIR]*  
Abstract 8579, Poster Session: Lung Cancer – Non-Small Cell Local-Regional/Small Cell/Other Thoracic Cancers, Date: Sunday, June 3, Time: 8:00 AM – 11:30 AM Location: Hall A

### **Copanlisib**

- *Copanlisib treatment in patients with relapsed or refractory indolent B-cell lymphoma: Subgroup analyses of diabetic patients from the phase II CHRONOS-1 study*  
Abstract 7570, Poster Session: Hematologic Malignancies – Lymphoma and Chronic Lymphocytic Leukemia, Date: Monday, June 4, Time: 8:00 AM – 11:30 AM, Location: Hall A
- *A phase Ib trial of copanlisib and trastuzumab in pretreated recurrent or metastatic HER2-positive breast cancer “PantHER” [IIR]*  
Abstract 1036, Poster Session: Breast Cancer – Metastatic, Date: Saturday, June 2, Time: 8:00 AM – 11:30 AM, Location: Hall A

### **Darolutamide**

- *ODENZA: A study of patient preference between ODM-201(darolutamide) and enzalutamide in men with metastatic castrate-resistant prostate cancer (mCRPC) [TIP] [IIR]*  
Abstract TPS5093, Poster Session: Genitourinary (Prostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 4:45 PM, Location: Hall A

### **Other pipeline abstracts**

- *Rogaratinib in patients with advanced urothelial carcinomas prescreened for tumor FGFR mRNA expression and effects of mutations in the FGFR signaling pathway*  
Abstract 4513, Poster Discussion Session: Genitourinary (Nonprostate) Cancer, Date: Saturday, June 2, Time: 1:15 PM – 2:30 PM
- *Location: Hall D2 Phase Ib study of anti-mesothelin antibody drug conjugate anetumab ravtansine in combination with pegylated liposomal doxorubicin in platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer*

Abstract 5571, Poster Session: Gynecologic Cancer, Date: Monday, June 4, Time: 1:15 PM – 4:45 PM, Location: Hall A

- *Phase 1b multi-indication study of the antibody drug conjugate anetumab ravtansine in patients with mesothelin-expressing advanced or recurrent malignancies [TIP]*

Abstract TPS2607, Poster Session: Developmental Therapeutics – Clinical Pharmacology and Experimental Therapeutics, Date: Monday, June 4, Time: 8:00 AM – 11:30 AM, Location: Hall A

- *Phase I dose escalation study of the first-in-class selective PTEFb inhibitor BAY 1251152 in patients with advanced cancer: Novel target validation and early evidence of clinical activity*

Abstract 2507, Oral Abstract cwSession: Developmental Therapeutics – Clinical Pharmacology and Experimental Therapeutics, Date: Friday, June 1, Time: 4:57 PM – 5:09 PM, Location: S406

### **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 four marketed products and several other assets 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**

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 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to [www.bayer.com](http://www.bayer.com).

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**Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at [www.bayer.com](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.