News Release

Not intended for U.S. and UK Media

Bayer to showcase latest oncology research at ESMO 2017

- Features findings from two ongoing trials evaluating radium-223 dichloride injection in metastatic castration-resistant prostate cancer and other solid tumors prone to bone metastases

- Further data on regorafenib in hepatocellular carcinoma (HCC), the late-stage compound copanlisib in lymphoma as well as early pipeline data to be presented


Berlin, September 1, 2017 – Bayer announced today the latest research from across its growing oncology portfolio that will be presented at the European Society for Medical Oncology (ESMO) 2017 Congress taking place September 8-12 in Madrid, Spain. The studies presented will include new preclinical and clinical data on already approved or late-stage compounds as well as research from two earlier pipeline projects.

Notable data for the company’s existing product portfolio include results from two ongoing trials for radium-223 dichloride (Xofigo®) injection, including an interim read-out from the observational REASSURE trial, analyzing real-world metastatic castration-resistant prostate cancer patient characteristics and safety profile.

Additionally, multiple exploratory analyses of the Phase III RESORCE trial of Stivarga® (regorafenib) in hepatocellular carcinoma (HCC) will be presented. In August, the European Commission (EC) granted marketing authorization for Stivarga for the treatment of adult patients with HCC who have been previously treated with Nexavar® (sorafenib), the first new treatment for HCC in a decade. The product has also received regulatory approvals for second-line HCC in other markets, including the U.S. and Japan.
Bayer will also present subgroup results from the pivotal Phase II CHRONOS-1 study of copanlisib in patients with relapsed or refractory indolent B-cell non-Hodgkin’s lymphoma. Copanlisib is a novel pan-class I PI3K inhibitor with predominant inhibitory activity against PI3K-α and PI3K-δ isoforms and has been granted priority review by the FDA. The compound is not approved by the FDA, the European Medicines Agency or any other health authority.

Notable Bayer studies at ESMO 2017 Congress include the following:

**Radium-223 Dichloride**
- First interim results of the radium-223 (Ra-223) REASSURE observational study: Analysis of patient (Pt) characteristics and safety by use of abiraterone and / or enzalutamide (Abi / Enza)
  - Abstract 807P, Session: Poster Display Session
  - Date: September 10, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8
- An open-label, multicenter phase Ib study of radium-223 + paclitaxel in cancer patients with bone metastases
  - Abstract 416P, Session: Poster Display Session
  - Date: September 11, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

**Regorafenib**
- Exploratory analysis of baseline microsatellite instability (MSI) status in patients with metastatic colorectal cancer (mCRC) treated with regorafenib (REG) or placebo in the phase 3 CORRECT trial
  - Abstract 534P, Session: Poster Display Session
  - Date: September 9, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8
- Circulating miRNA biomarkers predicting regorafenib (REG) clinical benefit in patients with hepatocellular carcinoma (HCC) in the RESORCE trial
  - Abstract 705P, Session: Poster Display Session
  - Date: September 9, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8
- Immunomodulation by regorafenib alone and in combination with anti PD1 antibody on murine models of colorectal cancer
  - Abstract 1198P, Session: Poster Display Session
  - Date: September 10, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

- Tumor growth rate analysis of progression-free survival (PFS) and overall survival (OS) for patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) receiving placebo or regorafenib in the phase 3 GRID trial
  - Abstract 1513P, Session: Poster Display Session
  - Date: September 11, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

- Protein biomarkers as predictors of outcome with regorafenib (REG) in patients (pts) with hepatocellular carcinoma (HCC) in the RESORCE trial
  - Abstract 625PD, Session: Poster Discussion Session
  - Date: September 11, 2017, Time: 5:20 pm - 5:40 pm CEST
  - Location: Cordoba Auditorium

- A phase Ib study evaluating the safety and pharmacokinetics (PK) of regorafenib (REG) in combination with cetuximab (CTX) in patients with advanced solid tumors
  - Abstract 380P, Session: Poster Display Session
  - Date: September 11, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

- Sorafenib
  - Correlation between overall survival (OS) and time to progression (TTP) and between OS and response rate (RR) by RECIST in advanced hepatocellular carcinoma (HCC)
    - Abstract 702P, Session: Poster Display Session
    - Date: September 9, 2017, Time: 1:15 pm - 2:15 pm CEST
    - Location: Hall 8

  - Overall survival (OS) by platelet count at baseline in patients with hepatocellular carcinoma (HCC) treated with sorafenib (SOR) in the SHARP and AP trials and regorafenib (REG) in the RESORCE trial
    - Abstract 706P, Session: Poster Display Session
    - Date: September 9, 2017, Time: 1:15 pm - 2:15 pm CEST
    - Location: Hall 8
Interim baseline characteristics from 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): A European subgroup analysis

- Abstract 465P, Session: Poster Display Session
- Date: September 10, 2017, Time: 1:15 pm - 2:15 pm CEST
- Location: Hall 8

**Copanlisib**

- Phase III randomized, double-blind, controlled studies of the PI3K inhibitor copanlisib in combination with rituximab or rituximab-based chemotherapy in subjects with relapsed indolent B-cell non-Hodgkin's lymphoma (iNHL): CHRONOS-3 and CHRONOS-4
  - Trial in Progress: Abstract 1034TiP, Session: Poster Display Session
  - Date: September 9, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

- Copanlisib treatment in patients with relapsed or refractory indolent B-cell lymphoma: Subgroup analyses from the CHRONOS-1 study
  - Abstract 1000PD, Session: Poster Discussion Session
  - Date: September 11, 2017, Time: 4:50 pm - 5:10 pm CEST
  - Location: Tarragona Auditorium

- Tumor gene expression signatures of BCR/PI3K dependence in association with copanlisib monotherapy activity in heavily pretreated patients with indolent NHL and follicular lymphoma
  - Abstract 1001PD, Session: Poster Discussion Session
  - Date: September 11, 2017, Time: 4:50 pm - 5:10 pm CEST
  - Location: Tarragona Auditorium

**Darolutamide**

- ARASENS: A Phase 3 Trial of Darolutamide in Males With Metastatic Hormone-Sensitive Prostate Cancer (mHSPC)
  - Trial in Progress: Abstract 838TiP, Session: Poster Display Session
  - Date: September 10, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8
Anetumab Ravtansine
- Phase Ib multi-indication study of the antibody drug conjugate anetumab ravtansine in patients with mesothelin-expressing advanced or recurrent malignancies
  - Trial in Progress: Abstract 424TiP, Session: Poster Display Session
  - Date: September 11, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

Rogaratinib
- Anti-tumor activity of the pan-FGFR inhibitor rogaratinib in patients with advanced urothelial carcinomas selected based on tumor FGFR mRNA expression levels
  - Abstract 859P, Session: Poster Display Session
  - Date: September 10, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8
- A novel mRNA-based patient selection strategy identifies fibroblast growth factor receptor (FGFR) inhibitor-sensitive tumors: Results from rogaratinib Phase-1 study
  - Abstract 379P, Session: Poster Display Session
  - Date: September 11, 2017, Time: 1:15 pm - 2:15 pm CEST
  - Location: Hall 8

About Radium-223 Dichloride (Xofigo®)
Radium-223 dichloride is a Targeted Alpha Therapy that 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 Regorafenib (Stivarga®)
Regorafenib, an oral mult-kinase inhibitor, is approved under the brand name Stivarga® in more than 90 countries worldwide, including the U.S., countries of the EU, China and Japan for the treatment of metastatic colorectal cancer (mCRC). The product is also approved in over 80 countries, including the U.S., countries of the EU, China 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 Sorafenib (Nexavar®)**

Sorafenib, an oral anti-cancer therapy, is approved under the brand name Nexavar® for the treatment of certain forms of hepatocellular carcinoma, renal cell carcinoma and differentiated thyroid carcinoma. Whilst licenses may differ from country to country, across all indications Nexavar is approved in more than 100 countries worldwide. In countries of the European Union, 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.

Bayer has worldwide exclusive marketing rights for Nexavar, with Bayer paying a royalty on US sales to Amgen Inc. Outside the U.S., Bayer and Amgen share profits globally, excluding Japan.

**About Copanlisib**

Copanlisib is an investigational anti-cancer agent developed by Bayer currently in Phase III of clinical development. The U.S. Food and Drug Administration (FDA) granted Priority Review designation for Bayer’s New Drug Application (NDA) for copanlisib for the treatment of relapsed or refractory FL patients who have received at least two prior therapies, based on the data from the Phase II CHRONOS-1 study. The compound is not approved by the FDA, the European Medicines Agency or any other health authority.

**About Darolutamide**

Darolutamide is a novel investigational oral androgen receptor (AR) antagonist, currently investigated in two Phase III studies in non-metastatic castration resistant prostate cancer as well as metastatic hormone-sensitive prostate cancer. The compound is not approved.
by the European Medicines Agency, U.S. Food and Drug Administration or any other health authority.

**About Anetumab Ravtansine**
Anetumab ravtansine is an antibody-drug conjugate (ADC) that specifically targets mesothelin, a surface marker protein overexpressed in many cancers. The compound is currently being investigated in a variety of mesothelin-positive tumors, including malignant pleural mesothelioma, ovarian cancer and six other types of advanced solid tumors. The compound is not approved by the European Medicines Agency, U.S. Food and Drug Administration or any other health authority.

**About Rogaratinib**
Rogaratinib (BAY 1163877) is an oral, small molecule pan-fibroblast growth factor receptor (FGFR) inhibitor of FGFRs 1-4 with antineoplastic activity demonstrated in preclinical studies. Rogaratinib is currently being investigated in patients with advanced solid tumors with high FGFR mRNA expression (NCT01976741). The compound is not approved by the European Medicines Agency, U.S. Food and Drug Administration or any other health authority.

**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 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.

**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.

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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. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.