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News Release

Not intended for U.S. and UK Media

2018 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium:

Bayer to showcase latest prostate cancer research at ASCO GU 2018 Cancer Symposium

- New data on the long-term efficacy and safety of Xofigo[®] (radium-223 dichloride)
 - Update on ongoing studies with darolutamide, a novel investigational oral androgen receptor (AR) antagonist, including the ARASENS pivotal trial in men with metastatic hormone-sensitive prostate cancer (mHSPC)
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Abstracts: 233, 178, TPS383, 345, 293

Berlin, February 7, 2018 – Bayer announced today that new prostate cancer data from the continued research on the long-term efficacy and safety of Xofigo[®] (radium-223 dichloride) and the ongoing clinical trial program with darolutamide, a novel investigational oral androgen receptor (AR) antagonist, will be presented at the 2018 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium taking place February 8-10 in San Francisco, California (U.S.).

Bayer will present data from the first interim analysis of REASSURE, a real-world, observational study to evaluate the safety of Xofigo in men with metastatic castration-resistant prostate cancer (mCRPC) in the U.S. In addition, efficacy and safety data from an international, open-label study in mCRPC patients who were re-treated with radium-223 dichloride will be presented.

Bayer will also present data and provide an update on ongoing studies with darolutamide, including the ARASENS pivotal trial in men with metastatic hormone-sensitive prostate cancer (mHSPC). This underlines Bayer's commitment to the prostate cancer community and Bayer's critical mission of serving those patients with the greatest unmet needs.

Notable studies at the ASCO GU 2018 Cancer Symposium include the following:

Radium-223 dichloride (radium-223)

- *First interim results of the radium-223 (Ra-223) REASSURE observational study in metastatic castration-resistant prostate cancer (mCRPC): Safety and baseline (BL) characteristics of U.S. patients (Pts) by prior/concomitant treatment (Tx)*
Abstract 233, BOARD L9, Poster Session A: Prostate Cancer and Trials in Progress; Thursday, February 8: 11:30 AM-1:00 PM and 5:15 PM-6:15 PM; Level 1, West Hall
- *Radium-223 retreatment in an international, open-label, phase 1/2 study in patients with castration-resistant prostate cancer and bone metastases: 2-year follow-up*
Abstract 178, BOARD H18, Poster Session A: Prostate Cancer and Trials in Progress; Thursday, February 8: 11:30 AM-1:00 PM and 5:15 PM-6:15 PM; Level 1, West Hall

Darolutamide

- *ARASENS: A phase 3 trial of darolutamide in combination with docetaxel for men with metastatic hormone-sensitive prostate cancer (mHSPC)*
Abstract TPS383, BOARD P1, Poster Session A: Prostate Cancer and Trials in Progress; Thursday, February 8: 11:30 AM-1:00 PM and 5:15 PM-6:15 PM; Level 1, West Hall
- *Blood Brain Barrier Penetration of [¹⁴C] Darolutamide Compared with [¹⁴C] Enzalutamide in Rats Using Whole Body Autoadiography*
Abstract 345, BOARD D14, Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers and Trials in Progress; Friday, February 9: 12:15 PM-1:45 PM and 6:00 PM-7:00 PM; Level 1, West Hall

General castration-resistant prostate cancer (CRPC)

- *Survival outcomes of pre-metastatic castration-resistant prostate cancer and the burden of developing metastasis: A systematic literature review*
Abstract 293, BOARD B4, Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, and Testicular Cancers and Trials in Progress; Friday, February 9: 12:15 PM-1:45 PM and 6:00 PM-7:00 PM; Level 1, West Hall

About radium-223 dichloride

Radium-223 dichloride (radium-223) is a Targeted Alpha Therapy. It selectively targets bone, specifically areas of bone metastases, by forming complexes with the bone mineral hydroxyapatite. The high linear energy transfer of alpha particles 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.

In countries of the EU, radium-223 dichloride is indicated for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases. The compound has already been approved in more than 50 countries worldwide, including the U.S., countries of the EU and Japan, under the brand name Xofigo®. 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 darolutamide

Darolutamide is a novel investigational oral androgen receptor (AR) antagonist with a specific chemical structure designed to block the growth of cancer cells by binding to the AR with high affinity and inhibiting the receptor function. In preclinical studies, darolutamide and its main circulating metabolite were also active in known AR mutations, such as W742L and F877L, with negligible blood-brain barrier penetration.

Darolutamide demonstrated promising anti-tumor activity in a Phase I/II study in patients with metastatic castration-resistant prostate cancer. 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 now includes four 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

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 99,600 people and had sales of EUR 34.9 billion. Capital expenditures amounted to EUR 2.2 billion, R&D expenses to EUR 4.4 billion. 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.