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News Release

Not intended for U.S. and UK Media

Bayer to showcase new data from its growing cancer portfolio at 2019 ASCO GU Cancers Symposium

First presentation of data from the pivotal Phase III ARAMIS trial with the investigational compound darolutamide in patients with advanced prostate cancer that has not yet metastasized

Abstracts: 140, 156, TPS334, 297, 253, TPS348, 323, 565

Berlin, February 5, 2019 – Bayer announced today that research on its growing cancer portfolio will be presented at the 2019 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium taking place February 14-16 in San Francisco.

Among the data presented will be the first results on the investigational cancer treatment darolutamide from the pivotal Phase III ARAMIS trial, a randomized, double-blind, placebo-controlled study to assess the safety and efficacy of darolutamide in patients with non-metastatic castration-resistant prostate cancer (nmCRPC) being treated with androgen deprivation therapy (ADT) and at high risk for developing metastatic disease. Darolutamide is being developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

Bayer plans to discuss data from the ARAMIS trial with health authorities regarding the submission of a new drug application. Darolutamide has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) in patients with nmCRPC.

Bayer will also present data on its approved prostate cancer treatment Xofigo® (radium-223 dichloride) and Nexavar® (sorafenib), approved for the treatment of certain forms of hepatocellular carcinoma, renal cell carcinoma and differentiated thyroid carcinoma,

including real-world outcomes and data analyses from across the ongoing clinical research program.

Notable darolutamide, Xofigo® and Nexavar® studies to be presented at the 2019 ASCO GU Cancers Symposium include:

Darolutamide

- *ARAMIS: Efficacy and safety of darolutamide in non-metastatic castration-resistant prostate cancer (nmCRPC)*
    - Abstract 140, Board A4, Poster Session A: Prostate Cancer and Trials in Progress, Oral Abstract Session A: Prostate Cancer
    - Date: Thursday, February 14: 11:30 AM-1:00 PM PST and 5:30 PM-6:30 PM PST (poster presentation), 1:45-1:55 PM PST (oral presentation)
- *Higher blood–brain barrier penetration of [^{14}C]apalutamide and [^{14}C]enzalutamide compared to [^{14}C]darolutamide in rats using whole-body autoradiography*
    - Abstract 156, Board F21, Poster Session A: Prostate Cancer and Trials in Progress
    - Date: Thursday, February 14: 11:30 AM-1:00 PM PST and 5:30 PM-6:30 PM PST
- *ODENZA: A study of patient preference between ODM-201 (darolutamide) and enzalutamide in men with metastatic castrate-resistant prostate cancer (mCRPC)*
    - Abstract TPS334, Board N10, Poster Session A: Prostate Cancer and Trials in Progress
    - Date: Thursday, February 14: 11:30 AM-1:00 PM PST and 5:30 PM-6:30 PM PST
- *Drug-drug interaction (DDI) of darolutamide with cytochrome P450 (CYP) and P-glycoprotein (P-gp) substrates: Results from clinical and in vitro studies*
    - Abstract 297, Board D5, Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, Testicular, and Adrenal Cancers
    - Date: Friday, February 15: 12:15 PM-1:45 PM PST and 5:15 PM-6:15 PM PST

Radium-223 Dichloride (radium-223)

- *Clinical outcome with concurrent or layered treatment with radium-223 and abiraterone: A retrospective study of real-world experience with patients (pts) with metastatic castration-resistant prostate cancer (mCRPC)*

    - Abstract 253, Board L10, Poster Session A: Prostate Cancer and Trials in Progress
    - Date: Thursday, February 14: 11:30 AM-1:00 PM PST and 5:30 PM-6:30 PM PST
- *A phase III trial of docetaxel versus docetaxel and radium-223 (Ra-223) in patients with metastatic castration-resistant prostate cancer (mCRPC): DORA*
    - Abstract TPS348, Board P2, Poster Session A: Prostate Cancer and Trials in Progress
    - Date: Thursday, February 14: 11:30 AM-1:00 PM PST and 5:30 PM-6:30 PM PST
- *Clinical outcomes of a Dutch prospective observational registry of metastatic castration resistant prostate cancer (mCRPC) patients treated with radium-223 (Ra-223)*
    - Abstract 323, Board E9, Poster Session B: Prostate Cancer, Urothelial Carcinoma, and Penile, Urethral, Testicular, and Adrenal Cancers
    - Date: Friday, February 15: 12:15 PM-1:45 PM PST and 5:15 PM- 6:15 PM PST

Sorafenib

- *Real-world use of sorafenib for advanced renal cell carcinoma patients with cardiovascular disease: Nationwide survey in Japan*
    - Abstract 565, Board E4, Poster Session C: Renal Cell Cancer
    - Date: Saturday, February 16: 7:00 AM-7:55 AM PST and 12:30 PM-2:00 PM PST

About Darolutamide

Darolutamide is a non-steroidal androgen receptor antagonist with a distinct chemical structure that binds to the receptor with high affinity and exhibits strong antagonistic activity, thereby inhibiting the receptor function and the growth of prostate cancer cells. Darolutamide has shown promising activity in Phase I/II studies in patients with mCRPC. A Phase III study in metastatic hormone-sensitive prostate cancer (ARASENS) is ongoing. Information about these trials can be found at www.clinicaltrials.gov.

Darolutamide is not approved by the U.S. FDA, the European Medicines Agency or any other health authority.

About Xofigo® (radium Ra 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 patients with metastatic castration-resistant prostate cancer (mCRPC), symptomatic bone metastases and no known visceral metastases, in progression after at least two prior lines of systemic therapy for mCRPC (other than LHRH analogues), or ineligible for any available systemic mCRPC treatment. 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®.

About Nexavar® (Sorafenib)
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 E.U., 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 U.S. sales to Amgen Inc. Outside the U.S., Bayer and Amgen share profits globally, excluding Japan.

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 five 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.

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