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News Release

Not intended for U.S. and UK Media

Bayer unveils latest data from prostate cancer portfolio at 2025 ASCO GU Cancers Symposium

- Bayer is committed to advancing innovation in prostate cancer care, showcasing new analyses from its comprehensive clinical trial program for darolutamide, which includes the ARANOTE, ARASENS, and ARAMON trials
- The company also highlights data on radium-223 dichloride in metastatic castration-resistant prostate cancer and biochemically recurrent prostate cancer

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Abstracts: 151, 143, 152, 150, 66, TPS432, 183, 180, 81, 99, 101

Berlin, February 11, 2025 – Bayer will present new data from its prostate cancer portfolio at the upcoming American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium, taking place in San Francisco, United States, from February 13-15, 2025. These presentations reinforce Bayer´s commitment to advancing innovative treatments that delay disease progression and extend survival across different stages of prostate cancer, while maintaining daily living.

Data for darolutamide will include analysis from the Phase III ARANOTE trial, evaluating efficacy and safety of darolutamide and androgen-deprivation therapy (ADT) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) by disease volume. Analyses from the Phase III ARASENS trial will be presented, including evaluating age-related efficacy and safety of darolutamide plus ADT and docetaxel in patients with mHSPC and concomitant granulocyte colony-stimulating factor (G-CSF) use in maintaining an efficacious dose and safe delivery of docetaxel in combination with darolutamide in patients with mHSPC. Lead-in phase results will be presented from the Phase II ARAMON trial, investigating darolutamide monotherapy in patients with castration-sensitive prostate cancer (CSPC) after biochemical recurrence (BCR) and other data will focus on clinical use and outcomes of androgen-receptor pathway

inhibitors triplet therapy for mHSPC. A trial-in-progress update will also be presented for the ongoing Phase III ARASTEP trial investigating darolutamide plus ADT in patients with high-risk BCR of prostate cancer.

Darolutamide is already approved under the brand name Nubeqa™ in combination with ADT and docetaxel for the treatment of patients with mHSPC in over 80 markets including the U.S., Japan, EU, and China. It is also approved in more than 85 countries around the world for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC), who are at high risk of developing metastatic disease.

In radiopharmaceuticals, investigator-initiated research on radium-223 dichloride without ADT in patients with BCR and positron emission tomography (PET) findings suspicious for metastatic bone disease not seen on conventional imaging will be presented. Investigator-initiated research will be presented investigating safety and efficacy of retreatment of mCRPC patients with radium-223 dichloride therapy in daily practice. Data from three Real World Evidence studies further elucidating current treatment patterns in patients with mCRPC will also be presented.

Details on selected abstracts from Bayer at the 2025 ASCO GU Cancers Symposium are listed below:

Darolutamide

- *Darolutamide plus ADT in patients with metastatic hormone-sensitive prostate cancer (mHSPC) by disease volume: Subgroup analysis of the phase 3 ARANOTE trial*
  - *Abstract:* 151; February 13, 2025. 11:25 AM – 12:45 PM PST
- *Age-related efficacy and safety of darolutamide plus androgen-deprivation therapy (ADT) and docetaxel in patients with metastatic hormone-sensitive prostate cancer (mHSPC): a subgroup analysis of ARASENS*
  - *Abstract:* 143; February 13, 2025. 11:25 AM – 12:45 PM PST
- *Concomitant G-CSF use in maintaining an efficacious dose and safe delivery of docetaxel in combination with darolutamide in patients with metastatic hormone sensitive prostate cancer (mHSPC): ARASENS, a phase 3 study*
  - *Abstract:* 152; February 13, 2025. 11:25 AM – 12:45 PM PST
- *Darolutamide monotherapy in patients with castration-sensitive prostate cancer (CSPC) after biochemical recurrence (BCR): ARAMON lead-in phase results*
  - *Abstract:* 150; February 13, 2025. 11:25 AM – 12:45 PM PST

- *Clinical use and outcomes of Androgen-Receptor pAthwAy inhibitors Triplet therapy for metastatic hormone-sensitive prostate cancer (ARAAT) – **Real World Evidence (RWE)***
  - *Abstract:* 66; February 13, 2025. 11:25 AM – 12:45 PM PST
- *Darolutamide plus androgen-deprivation therapy (ADT) in patients with high-risk biochemical recurrence (BCR) of prostate cancer: A phase 3, randomized, double-blind, placebo-controlled study (ARASTEP) - **Trial in Progress (TiP)***
  - *Abstract:* TPS432; February 13, 2025. 11:25 AM – 12:45 PM PST

Radium-223 dichloride

- *Re-treatment of metastatic castration-resistant prostate cancer patients with radium-223 therapy in daily practice - **Investigator-Initiated Research (IIR)***
  - *Abstract:* 183; February 13, 2025. 11:25 AM – 12:45 PM PST
- *Radium 223 without Androgen Deprivation Therapy (ADT) in Patients (Pts) with Biochemically Recurrent Prostate Cancer (BCR) and PET Findings in the Bones - **Investigator-Initiated Research (IIR)***
  - *Abstract:* 180; February 13, 2025. 11:25 AM -12:45 PM PST
- *Effectiveness and safety of radium-223 in men with metastatic castration-resistant prostate cancer (mCRPC): A systematic literature review of 48 real-world studies – **Real World Evidence (RWE)***
  - *Abstract:* 81; February 13, 2025. 11:25 AM – 12:45 PM PST
- *Real-world treatment patterns and survival in men with metastatic castration-resistant prostate cancer (mCRPC) who previously progressed from metastatic hormone-sensitive prostate cancer (mHSPC) between 2020 to 2023 in the United States – **Real World Evidence (RWE)***
  - *Abstract:* 99; February 13, 2025. 11:25 AM -12:45 PM PST
- *Treatment patterns and survival in men with metastatic castration-resistant prostate cancer (mCRPC): A systematic literature review of 35 real-world observational studies – **Real World Evidence (RWE)***
  - *Abstract:* 101; February 13, 2025. 11:25 AM -12:45 PM PST

About Xofigo™

Xofigo™ is a therapeutic alpha particle-emitting pharmaceutical that emits radioactive alpha radiation and thus acts specifically against the cancer cells in the bones. In the EU, Xofigo monotherapy or in combination with luteinising hormone releasing hormone (LHRH) analogue is indicated for the treatment of adult 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.

About Prostate Cancer at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The company has the passion and determination to develop new medicines that help improve and extend the lives of people living with cancer. Prostate cancer is the second most commonly diagnosed cancer in men[1] and a key area of focus for Bayer. The company's franchise includes two products on the market (Nubeqa™ and Xofigo™) and several compounds in development. Bayer is focused on addressing the unique needs of patients with prostate cancer, providing treatments that extend their lives throughout the different stages of the disease and allowing them to continue with their everyday activities, so that patients can live longer, better lives.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. 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.