UNDER EMBARGO until Monday 8th February at 5pm ET / 11PM CET

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News Release

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New data presented at 2021 ASCO GU Cancers Symposium add to robustness of the overall survival benefit and favorable safety profile for Nubeqa™

- New analyses from the Phase III ARAMIS trial further strengthen the overall survival benefit and favorable safety profile of darolutamide (Nubeqa™) in men with non-metastatic castration-resistant prostate cancer (nmCRPC)
- Additional data from darolutamide and radium-223 dichloride (Xofigo™) trials demonstrate Bayer's continued commitment to ongoing prostate cancer research to bring meaningful benefit to the lives of men across different stages of the disease
- Expert-led and patient perspectives as well as additional prostate cancer educational resources for media can be found on Bayer's ASCO GU Virtual Media Hub

Abstracts: 239, 240, 217, TPS266, 105, 135, TPS182, 48, 98, TPS175, 136

Berlin, February 8, 2021 – Bayer announced today that new darolutamide (Nubeqa™) and radium-223 dichloride (Xofigo™) data will be presented at the 2021 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium, taking place from February 11-13, 2021. These results continue to demonstrate darolutamide's overall survival (OS) benefit and favorable safety profile over a prolonged treatment period, with a median treatment duration of 25.8 months, in men with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk for developing metastatic disease.

Prostate cancer is the second most commonly diagnosed cancer in men and is a key area of focus for Bayer. The data to be showcased at ASCO GU 2021 further build on the company's ongoing research to address the unique needs of this patient population so that men with prostate cancer can be offered effective treatment options throughout the different stages of disease, while reducing the burden of treatment side effects. Bayer's advancing prostate cancer portfolio is a pivotal element of the company's wider

commitment as an oncology leader to key areas of innovation, including Bayer's unique approach of advancing targeted alpha therapies and recently acquired expertise in cell and gene therapy, to ultimately meet the needs of people living with cancer.

"Approved therapies for nmCRPC increase metastasis-free and overall survival, but the treatment decisions should also consider the potential side effects of long-term treatment," said Matthew Smith, M.D., Ph.D., Director of the Genitourinary Malignancies Program, Massachusetts General Hospital Cancer Center. "The new data highlight the favorable safety profile of long-term treatment with darolutamide for men with nmCRPC."

Clinician, patient and patient advocate perspectives on the latest darolutamide data and the importance of patient-centricity in prostate cancer research are also available on Bayer's ASCO GU Virtual Media Hub.

Notable data to be presented at the meeting and additional information on the full data are listed below. More details on meeting registration can be found here.

Darolutamide

- *Safety of darolutamide (DARO) for nonmetastatic castration-resistant prostate cancer (nmCRPC) from extended follow-up in the phase III ARAMIS trial*
    - At the final analysis, the median treatment duration for patients randomized to darolutamide was 18.5 months for the double-blind (DB) period and 25.8 months for the DB + open-label (OL) period.
    - Results demonstrated that prolonged darolutamide treatment exposure was well-tolerated, with 48.8% of patients in the darolutamide DB+OL group still receiving darolutamide treatment at cut-off.
    - **Abstract 239; February 11, 8:00am EST**

- *Analysis of the effect of crossover from placebo (PBO) to darolutamide (DARO) on overall survival (OS) benefit in the ARAMIS Trial*
    - After unblinding, 170 patients (30.7% of those randomized to placebo) crossed over from placebo to darolutamide. Significant OS benefit was observed regardless of crossover. These results confirm that early treatment should be favored over delayed start of a life-prolonging therapy such as darolutamide.

- The safety profile of darolutamide continued to be favorable at the final analysis.
- **Abstract 240; February 11, 8:00am EST and 4:30pm EST**

- *Frequency, management, and resource use of adverse events (AEs) in nonmetastatic castrate-resistant prostate cancer (nmCRPC) patients receiving apalutamide or enzalutamide: A real-world study*
  - A real-world study showed the clinical and resource use burden of AEs among nmCRPC patients treated with enzalutamide or apalutamide and demonstrated safety and tolerability are key considerations in shared clinician-patient decision-making in this area.
  - **Abstract 217; February 11, 8:00am EST**

- *DASL-HiCaP: Darolutamide augments standard therapy for localized very high-risk cancer of the prostate (ANZUP1801)—A randomized phase III double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation* **– Investigator-Initiated Research (IIR)**
  - Ongoing DASL-HiCaP study assesses the metastasis-free survival (MFS) of darolutamide in addition to androgen deprivation therapy (ADT) and definitive or salvage radiation in men with either very high-risk localized prostate cancer, or very high risk features with prostate-specific antigen (PSA) persistence or rise within one year following radical prostatectomy, suitable for radiation therapy.
  - **Abstract TPS266; February 11, 8:00am EST**

Radium-223 dichloride (Ra-223)

- *Synergistic antitumor efficacy of radium-223 and enzalutamide in the intratibial LNCaP prostate cancer xenograft model*
  - These preclinical results showed that radium-223 in combination with enzalutamide displayed synergistic antitumor efficacy by decreasing PSA levels in the LNCaP intratibial model and was not observed to compromise bone health in healthy tibiae.
  - **Abstract 105; February 11, 8:00am EST**

- *Randomized phase II trial of radium-223 (RA) plus enzalutamide (EZ) versus EZ alone in metastatic castration-refractory prostate cancer (mCRPC): Final efficacy and safety results* **– Investigator-Initiated Research (IIR)**
    - Radium-223 + enzalutamide resulted in significant long-term clinical benefit when compared to enzalutamide alone in mCRPC patients, without compromising safety.
    - **Abstract 135; February 11, 8:00am EST and 4:30pm EST**

- *A phase I/II study of combination olaparib and radium-223 in men with metastatic castration-resistant prostate cancer with bone metastases (COMRADE): A trial in progress* **– Investigator-Initiated Research (IIR)**
    - The open-label, multi-center, phase 1/2 study will be evaluating the dosing, safety and efficacy of olaparib in combination with radium-223 in men with mCRPC with bone metastases.
    - **Abstract TPS182; February 11, 8:00am EST**

- *Real-world clinical outcomes study of sequential novel antihormonal therapy (NAH) or radium-223 (Ra-223) treatment of metastatic castration-resistant prostate cancer (mCRPC) that progressed after first-line NAH*
    - Among men with mCRPC in U.S. routine clinical practice, after failure of first-line (1L) NAH:
        - Patients with bone-only metastases, shorter duration of 1L NAH therapy, or prior symptomatic skeletal events (SSEs) were likely to receive second-line (2L) radium-223.
        - Patients receiving 2L radium-223 received subsequent therapies to a similar extent as those receiving 2L alternative NAH demonstrating the feasibility of further systemic treatment including chemotherapy after radium-223.
    - **Abstract 48; February 11, 8:00am EST**

- *Randomized phase II study evaluating the addition of pembrolizumab to radium-223 in metastatic castration-resistant prostate cancer* **– Investigator-Initiated Research (IIR)**
    - Results from the Phase II study demonstrated that while bone biopsies were hampered by nondiagnostic sampling, there was no evidence for increased CD4+/CD8+ T cell infiltration with the combination of radium-223 with

pembrolizumab, and no evidence for prolongation of radiographic progression-free survival (rPFS) or OS compared to radium-223 alone. Radium-223 + pembrolizumab can be safely combined with no unexpected toxicities.
    - **Abstract 98; February 11, 8:00am EST**

- *Fractionated docetaxel and radium-223 (Ra223) in metastatic castration-resistant prostate cancer (CRPC): A phase I trial* **– Investigator-Initiated Research (IIR)**
    - The study will evaluate whether fractionated dose-schedule of docetaxel bi-weekly (DQ2) in combination with standard radium-223 dosing will be feasible without reduction in dose-intensity of radium-223 or docetaxel.
    - **Abstract TPS175; February 11, 8:00am EST**

- *Clinical outcomes of patients with metastatic castration-resistant prostate cancer (mCRPC) receiving radium-223 (Ra-223) early versus late in the treatment sequence*
    - Real-world data from Ontario suggests that patients who received radium-223 in 2L versus third-line (3L) or later had better outcomes.
    - **Abstract 136; February 11, 8:00am EST**

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 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, including a unique approach of advancing targeted alpha therapies. 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 their everyday activities, so that they 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. Its products and services are designed to benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global

population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

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