Bayer to highlight data from its expanding cancer portfolio at 2020 ASCO GU Cancers Symposium

- New data to be presented on the potential impact of darolutamide on cognitive function in men with non-metastatic castration-resistant prostate cancer (nmCRPC)
- 18 presentations feature data on radium-223 dichloride, including real-world analyses and investigational combination therapies in men with advanced prostate cancer

**Abstracts:** 326, TPS384, 130, 32, 50, 56, 125, 41, 89, 59, 136, 121, 117, 47, 73, TPS267, 223, 236, 228, 225

**Berlin, February 13, 2020** – Bayer announced today that data from the company’s evolving oncology portfolio will be presented at the 2020 American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers Symposium, taking place February 13-15, 2020 in San Francisco, California (U.S.). The presentations across the latest research for Bayer’s marketed and pipeline therapies highlight the company’s ongoing commitment to exploring the potential of its therapies across different indications and treatment settings.

New data on the impact of darolutamide (Nubeqa®) on cerebral blood flow and cognitive function compared to enzalutamide in men with non-metastatic castration-resistant prostate cancer (nmCRPC) will be presented. Darolutamide, an androgen receptor inhibitor (ARI) jointly developed by Bayer and Orion Corporation, is approved in the U.S., Japan and Brazil, and recently received a positive CHMP opinion in the European Union (EU).

The research presented from Bayer’s prostate cancer portfolio will also include 18 presentations that feature real-world and combination studies with radium-223 dichloride (Xofigo®) in men living with advanced prostate cancer. Among these is the first presentation of data from a randomized Phase II study of sipuleucel-T (SipT) with or
without radium-223 dichloride in men with asymptomatic metastatic castration-resistant prostate cancer (mCRPC).

Notable presentations at ASCO GU 2020 are listed below:

**Darolutamide**
- *Significant localized reduction in cerebral blood flow (CBF) in regions relevant to cognitive function with enzalutamide (ENZA) compared to darolutamide (DARO) and placebo (PBO) in healthy volunteers*
  - Abstract: 326, Poster Session A: Prostate Cancer; Board M10
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- *INTREPID (INTermediate Risk Erection Preservation Trial): A randomized trial of radiation therapy and darolutamide for prostate cancer*
  - Abstract: TPS384, Trials in Progress Poster Session A: Prostate Cancer; Board Q4
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)

**Radium-223 dichloride (Ra-223)**
- *Randomized phase II study of sipuleucel-T (SipT) with or without radium-223 (Ra223) in men with asymptomatic bone-metastatic castrate-resistant prostate cancer (mCRPC) – Investigator initiated research (IIR)*
  - Abstract: 130, Poster Session A: Prostate Cancer; Board F10
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- *Clinical outcomes and patient (pt) profiles in REASSURE: An observational study of radium-223 (Ra-223) in metastatic castration-resistant prostate cancer (mCRPC)*
  - Abstract: 32, Poster Session A: Prostate Cancer; Board A20
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- *Concurrent or layered treatment (Tx) with radium-223 (Ra-223) and enzalutamide (Enza) or abiraterone plus prednisone/prednisolone (Abi/pred): a retrospective study of real-world clinical outcomes in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC)*
  - Abstract: 50, Poster Session A: Prostate Cancer; Board B16
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- *Variance in symptom assessment between patient and caregiver: a prospective study of patients staged as metastatic prostate cancer – an interim analysis – IIR*
  - Abstract: 56, Poster Session A: Prostate Cancer; Board B22
- Randomized phase II trial of radium-223 (RA) plus enzalutamide (EZ) versus EZ alone in metastatic castration-refractory prostate cancer (mCRPC): Long-term follow up of secondary endpoints – IIR
  - Abstract: 125, Poster Session A: Prostate Cancer; Board F5
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Fracture rates in radium223 (Ra223) treated mCRPC patients (pts): A real-world analysis in 177 pts treated at a single community center 2010-2018
  - Abstract: 41, Poster Session A: Prostate Cancer; Board B7
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- PRINT: Prostate Cancer Intensive, Non-Cross Reactive Therapy for CRPC – Early Observations of Efficacy – IIR
  - Abstract: 89, Poster Session A: Prostate Cancer; Board D13
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- The National Radium-223 Dichloride Audit Group: data from patients in United Kingdom oncology centers with metastatic castration-resistant prostate cancer treated with radium-223 dichloride – IIR
  - Abstract: 59, Poster Session A: Prostate Cancer; Board C3
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Results of the ADRRAD Trial of pelvic IMRT plus radium-223 in men with mHSPC metastatic to bone – IIR
  - Abstract: 136, Poster Session A: Prostate Cancer; Board F16
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Overall survival using radium-223 (Ra223) in metastatic castrate-resistant prostate cancer (mCRPC) patients with and without DNA damage repair (DDR) defects.
  - Abstract: 121, Poster Session A: Prostate Cancer; Board F1
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Analysis of prevalence and prognostic implications of early versus delayed PSA declines during radium-223 (Ra223) treatment among men with metastatic castration-resistant prostate cancer (mCRPC)
  - Abstract: 117, Poster Session A: Prostate Cancer; Board E19
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Who is a bone-predominant patient to maximize clinical benefits of radium-223 dichloride?
  - Abstract: 47, Poster Session A: Prostate Cancer; Board B13
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- The effect of docetaxel, enzalutamide, abiraterone, and radium-223 on cognitive function in older men with metastatic castrate-resistant prostate cancer (mCRPC)
  - Abstract: 73, Poster Session A: Prostate Cancer; Board C17
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Prospective trial of nivolumab (Nivo) plus radium-223 (RA) in metastatic castration-resistant prostate cancer (mCRPC) evaluating circulating tumor DNA (ctDNA) levels as a biomarker of response
  - Abstract: TPS267, Trials in Progress Poster Session A: Prostate Cancer; Board P11
  - February 13, 11:30am – 1:00pm, 5:30 – 6:30pm (PST)
- Real-world utilization of radium-223 (Ra-223) for the treatment of metastatic castration-resistant prostate cancer (mCRPC): a U.S. tertiary oncology center analysis
  - Abstract: 223, Poster Session B: Prostate Cancer; Urothelial Carcinoma; Penile, Urethral, Testicular, and Adrenal Cancers; Board B1
  - February 14, 12:15 – 1:45pm, 5:15 – 6:15pm (PST)
- Safety and effectiveness of radium-223 dichloride (Ra-223) in patients with mCRPC in real-world setting: A Japanese post-marketing study (PMS)
  - Abstract: 236, Poster Session B: Prostate Cancer; Urothelial Carcinoma; Penile, Urethral, Testicular, and Adrenal Cancers; Board B14
  - February 14, 12:15 – 1:45pm, 5:15 – 6:15pm (PST)
- Radium-223 in the treatment of metastatic castrate-resistant prostate cancer: A real-world Irish experience
  - Abstract: 228, Poster Session B: Prostate Cancer; Urothelial Carcinoma; Penile, Urethral, Testicular, and Adrenal Cancers; Board B6
  - February 14, 12:15 – 1:45pm, 5:15 – 6:15pm (PST)
- Prognostic factors that affect survival outcomes in men with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223
  - Abstract: 225, Poster Session B: Prostate Cancer; Urothelial Carcinoma; Penile, Urethral, Testicular, and Adrenal Cancers; Board B3
  - February 14, 12:15 – 1:45pm, 5:15 – 6:15pm (PST)

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 expands to six 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 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 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 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.