News Release

Bayer to Present Data from Growing Oncology Portfolio at the ASCO20 Virtual Scientific Program

- Data on final analysis of overall survival (OS) from the Phase III ARAMIS trial investigating darolutamide (Nubeqa™) in men with non-metastatic castration-resistant prostate cancer (nmCRPC)
- Updated efficacy and safety data for larotrectinib (Vitrakvi™) from an expanded set of adult patients with TRK fusion cancer and a quality of life (QoL) analysis in adult and pediatric patients
- New safety and efficacy data from established compounds including radium-223 dichloride (Xofigo™) and regorafenib (Stivarga™)

Abstracts: 5514, 5561, TPS5593, TPS5587, 5551, 3610, 3614, TPS10560, 5542, TPS5594, TPS5586, 5540, 5565, 4019, 10507, 3593, TPS4114, 3506

Berlin, May 11, 2020 – Data from Bayer’s growing oncology portfolio will be presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, taking place from May 29-31, 2020. Presentations will feature data across approved products, exploring therapies across different tumor types and treatment settings. Information on the registration as well as the virtual scientific program can be found here.

Data on the final analysis of overall survival (OS) from the Phase III ARAMIS trial investigating darolutamide (Nubeqa™) in men with non-metastatic castration-resistant prostate cancer (nmCRPC) will be presented in a virtual poster discussion on May 29, 2020. In January 2020, it was announced that results showed a statistically significant improvement in OS in patients receiving darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT. A separate analysis on safety outcomes between darolutamide, apalutamide and enzalutamide using matching-adjusted indirect comparison (MAIC), a method to perform indirect treatment comparisons adjusting for cross-trial heterogeneity, will also be presented. Darolutamide, an oral androgen receptor

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inhibitor (ARi) developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company, is indicated for the treatment of men with nmCRPC, who are at high risk of developing metastatic disease. The compound is approved under the brand name Nubeqa™ in the European Union (EU), U.S., Australia, Brazil, Canada, and Japan.

Updated efficacy and safety data for larotrectinib (Vitrakvi™) from an expanded set of adult patients with TRK fusion cancer and a quality of life (QoL) analysis in adult and pediatric patients treated with larotrectinib will be presented at the meeting. Vitrakvi is approved in the U.S., Canada, Brazil and the EU. While local labels might differ, the product indication spans across all solid tumors that harbor an \textit{NTRK} gene fusion. Additional filings in other regions are underway or planned.

Additional presentations from Bayer's other brands include data from the Phase II trial studying radium-223 dichloride (Xofigo™) and niraparib in metastatic castration-resistant prostate cancer (mCRPC) with and without prior chemotherapy and a second interim analysis from radium-223 REASSURE study evaluating safety and OS in patients with mCRPC. The trial design of the ongoing Phase III collaboration DORA study of docetaxel versus docetaxel and radium-223 dichloride is also presented. An investigator-initiated Phase I study of regorafenib (Stivarga™) in combination with vincristine and irinotecan in pediatric patients with recurrent or refractory solid tumors is featured as an oral presentation. Preliminary results of an investigator-initiated Phase II study (REGOMUNE) investigating regorafenib plus avelumab in a certain colorectal cancer (CRC) cohort will provide additional insights into the combination of regorafenib with an immune checkpoint inhibitor.

Notable presentations at ASCO20 Virtual Scientific Program are listed below and will be available online beginning May 29, 2020 at 8:00 AM ET:

**Darolutamide**

- Overall survival (OS) results of phase III ARAMIS study of darolutamide (DARO) added to androgen deprivation therapy (ADT) for non-metastatic castration-resistant prostate cancer (nmCRPC)
  - Abstract: 5514, Genitourinary Cancer – Prostate, Testicular, and Penile
- Safety outcomes of darolutamide versus apalutamide and enzalutamide in non-metastatic castration-resistant prostate cancer (nmCRPC): Matching-adjusted indirect comparisons
  o Abstract: 5561, Genitourinary Cancer – Prostate, Testicular, and Penile
- DAROL: DARolutamide Observational study patients in non-metastatic castration-resistant prostate cancer (nmCRPC) patients – Trial in Progress
  o Abstract: TPS5593, Genitourinary Cancer – Prostate, Testicular, and Penile
- DaroACT: Darolutamide and enzalutamide effects on physical and neurocognitive function and daily activity in patients with castration-resistant prostate cancer (CRPC) – Trial in Progress
  o Abstract: TPS5587, Genitourinary Cancer – Prostate, Testicular, and Penile
- Prostate Cancer Biomarker Enrichment and Treatment Selection (PC-BETS) Study: A Canadian Cancer Trials Group Phase 2 Umbrella Trial for Metastatic Castration-Resistant Prostate Cancer (mCRPC) – Investigator-Initiated Research (IIR)
  o Abstract: 5551, Genitourinary Cancer – Prostate, Testicular, and Penile

Larotrectinib
- Activity and safety of larotrectinib in adult patients with TRK fusion cancer: An expanded data set
  o Abstract: 3610, Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
- Quality of life of adults and children with TRK fusion cancer treated with larotrectinib compared to the general population
  o Abstract: 3614, Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
- A phase II study of larotrectinib for children with newly diagnosed solid tumors and relapsed acute leukemias harboring TRK fusions: Children’s Oncology Group study ADVL1823 – Trial in Progress; IIR
  o Abstract: TPS10560, Pediatric Oncology

Radium-223 dichloride (Ra-223)
- Safety and overall survival (OS) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223 (Ra-223) plus subsequent taxane therapy
  o Abstract: 5542, Genitourinary Cancer – Prostate, Testicular, and Penile
• A phase III trial of docetaxel versus docetaxel and radium-223 (Ra-223) in patients with metastatic castration-resistant prostate cancer (mCRPC): DORA – Trial in Progress
  o Abstract: TPS5594, Genitourinary Cancer – Prostate, Testicular, and Penile
• A phase II randomized trial of RAdium-223 dichloride and SABR versus SABR for oligoMetastatic prostate caNcerS (RAVENS) – Trial in Progress; IIR
  o Abstract: TPS5586, Genitourinary Cancer – Prostate, Testicular, and Penile
• Radium-223 (Rad) and niraparib (Nira) treatment (tx) in castrate-resistant prostate cancer (CRPC) patients (pts) with and without prior chemotherapy (chemo) – IIR
  o Abstract: 5540, Genitourinary Cancer – Prostate, Testicular, and Penile
• Safety and clinical activity of atezolizumab (atezo) + radium-223 dichloride (r-223) in 2L metastatic castration-resistant prostate cancer (mCRPC): Results from a phase Ib clinical trial
  o Abstract: 5565, Genitourinary Cancer – Prostate, Testicular, and Penile

Regorafenib
• REGOMUNE: A phase II study of regorafenib (R) plus avelumab (A) in solid tumors, preliminary results of the non-MSI-H metastatic colorectal cancer (CRC) cohort – IIR
  o Abstract: 4019, Gastrointestinal Cancer – Colorectal and Anal
• Phase 1 study of regorafenib in combination with vincristine and irinotecan in pediatric patients with recurrent or refractory solid tumors
  o Abstract: 10507, Pediatric Oncology
• Phase 1 study of regorafenib and sildenafil in advanced solid tumors – IIR
  o Abstract: 3593, Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology

Copanlisib
• A phase I/II study of PI3Kinase inhibition with copanlisib combined with the anti-PD-1 antibody nivolumab in relapsed/ refractory solid tumors with expansions in MSS colorectal cancer – IIR
  o Abstract: TPS4114, Gastrointestinal Cancer – Colorectal and Anal
• Phase II Study of copanlisib in patients with tumors with PIK3CA mutations (PTEN loss allowed): NCI MATCH EAY131-Z1F – IIR
  o Abstract: 3506, Developmental Therapeutics – Molecularly Targeted Agents and Tumor Biology
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 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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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.