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News Release

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Bayer to present key data across oncology portfolio showcasing significant advances in cancer care at 2022 ASCO Annual Meeting

- Prostate cancer remains a key focus area with darolutamide data in non-metastatic castration-resistant prostate cancer (high-risk nmCRPC) and metastatic hormone-sensitive prostate cancer (mHSPC), and radium-223 dichloride research in metastatic castration-resistant prostate cancer (mCRPC)
- Presentations of larotrectinib include long-term efficacy and safety data for patients with TRK fusion cancer from integrated and expanded analyses, updated health-related quality of life (QoL) of patients with TRK fusion cancer and sub-analyses for TRK fusion cancer patients with primary central nervous system (CNS) tumors and lung cancer, respectively
- Poster data featuring regorafenib and sorafenib will also be displayed

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Abstracts: 5078, 5044, TPS5111, 5038, 5040, 5041, 10030, 3100, 9024, 2010, 6563, 6597, 10006, 4060, 3561, TPS11585, 4125, 11555, 12040

Berlin, May 19, 2022 – Bayer will present new data across its oncology portfolio at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting from June 3-7, 2022. These presentations continue to reinforce Bayer's position as an innovator in oncology and ongoing dedication to advancing oncology treatments for patients on a global scale.

Darolutamide data presented will include overall survival (OS) and prostate-specific antigen (PSA) results from the Phase III ARASENS trial in metastatic hormone-sensitive prostate cancer (mHSPC) and results of a post-hoc analysis from the Phase III ARAMIS trial in high-risk non-metastatic castration-resistant prostate cancer (nmCRPC). Darolutamide is an androgen receptor inhibitor (ARi) with a distinct chemical structure that competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated

transcription. Darolutamide is approved under the brand name Nubeqa™ in more than 60 countries around the world, including the U.S., European Union (EU), Japan, and China, for the treatment of patients with nmCRPC who are at high risk of developing metastatic disease. Bayer recently submitted applications in mHSPC to the Food and Drug Administration (FDA), the European Medicine Agency (EMA), the Ministry of Health, Labor and Welfare (MHLW) in Japan, and China's Center of Drug Evaluation (CDE). Darolutamide is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

Research on radium-223 dichloride will also be highlighted, including results from an interim analysis of the RALU study, which evaluated safety and survival outcomes in patients with metastatic castration-resistant prostate cancer (mCRPC) treated with lutetium-177-prostate-specific membrane antigen (^{177}Lu-PSMA) after radium-223 dichloride as well as alkaline phosphatase (ALP) decline and OS data in mCRPC patients treated with radium-233 dichloride in the REASSURE study. Xofigo™ is indicated for the treatment of patients with mCRPC, symptomatic bone metastases, and no known visceral metastatic disease, 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.

Efficacy and safety findings of larotrectinib for patients with TRK fusion cancer from an integrated pooled analysis per an independent review committee (IRC) assessment, efficacy and safety data from an expanded dataset, updated health-related quality of life (QoL) of adult and pediatric patients with TRK fusion cancer, and sub-analyses for TRK fusion cancer patients with primary central nervous system (CNS) tumors and lung cancer, respectively, will be shared. Additional data for larotrectinib include an analysis in adult and pediatric patients evaluating larotrectinib compared to standard of care using a matching-adjusted indirect comparison (MAIC). MAIC is an alternative method for comparative data when a randomized control trial (RCT) is not available and/or possible, as for a rare condition like TRK fusion cancer. Results from these studies bolster larotrectinib's existing clinical profile in TRK fusion cancer across a variety of tumor types and ages. Vitrakvi™, the first treatment to receive a tumor-agnostic indication in the EU, is approved in more than 40 countries, including the U.S. and most recently in China for pediatric and adult patients with *NTRK* fusion-positive advanced or recurrent solid tumors. Additional filings in other regions are underway or planned.

Other research includes investigator-initiated research (IIR) for regorafenib and sorafenib in several areas of oncology.

Presentations from Bayer and IIR projects for the 2022 ASCO Annual Meeting are listed below:

Darolutamide

- *Association of prostate-specific antigen (PSA) response and overall survival (OS) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) from the phase 3 ARASENS trial*
    - Abstract 5078; June 6, 2:15pm EDT
- *Progression patterns by types of metastatic spread, prostate-specific antigen (PSA), and clinical symptoms: Post-hoc analyses of ARAMIS*
    - Abstract 5044; June 6, 2:15pm EDT
- *Open-label study of androgen receptor inhibition with darolutamide plus androgen-deprivation therapy (ADT) versus ADT in men with metastatic hormone-sensitive prostate cancer using an external control arm (ARASEC) –* ***Trial in Progress (TiP)***
    - Abstract TPS5111; June 6, 2:15pm EDT
- *Influence of darolutamide on cabazitaxel systemic exposure –* ***Investigator-Initiated Research (IIR)***
    - Abstract 5038; June 6, 2:15pm EDT

Radium-223 dichloride (Ra-223)

- *Safety and survival outcomes in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated with lutetium-177-prostate-specific membrane antigen (^{177}Lu-PSMA) after radium-223 (^{223}Ra): Interim analysis of the RALU study*
    - Abstract 5040; June 6, 2:15pm EDT
- *Alkaline phosphatase (ALP) decline and overall survival (OS) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223 (Ra-223) in the REASSURE Study*
    - Abstract 5041; June 6, 2:15pm EDT

Larotrectinib

- *Efficacy and safety of larotrectinib in pediatric patients with tropomyosin receptor kinase (TRK) fusion-positive cancer: An expanded dataset*
    - Abstract 10030; June 6, 9:00am EDT

- *Long-term efficacy and safety of larotrectinib in a pooled analysis of patients with tropomyosin receptor kinase (TRK) fusion cancer*
    - Abstract 3100; June 5, 9:00am EDT
- *Updated efficacy and safety of larotrectinib in patients with tropomyosin receptor kinase (TRK) fusion lung cancer*
    - Abstract 9024; June 6, 2:15pm EDT
- *Long-term control and safety of larotrectinib in a cohort of adult and pediatric patients with tropomyosin receptor kinase (TRK) fusion primary central nervous system (CNS) tumors*
    - Abstract 2010; June 5, 12:30pm EDT
- *Updated health-related quality of life of patients with TRK-fusion cancer treated with larotrectinib in clinical trials*
    - Abstract 6563; June 6, 2:15pm EDT
- *Overall survival (OS) of patients with TRK fusion-positive cancer receiving larotrectinib versus standard of care (SoC): A matching-adjusted indirect comparison (MAIC) using real-world data (RWD)*
    - Abstract 6597; June 6, 2:15pm EDT
- *Securing access to innovative anticancer therapies for children, adolescents and young adults outside clinical trials: The SACHA study of the French Society of Pediatric Oncology (SFCE) –* ***Investigator-Initiated Research (IIR)***
    - Abstract 10006; June 6, 5:36pm EDT

Regorafenib

- *REGOMUNE: A phase II study of regorafenib plus avelumab in solid tumors—Results of the oesophageal or gastric carcinoma (OGC) cohort –* ***Investigator-Initiated Research (IIR)***
    - Abstract 4060; June 4, 9:00am EDT
- *REGOMUNE: Phase II study of regorafenib plus avelumab in solid tumors—Results of the gastroenteropancreatic neuroendocrine carcinomas (GEP-NEC) cohort –* ***Investigator-Initiated Research (IIR)***
    - Abstract 4125; June 4, 9:00am EDT
- *Regorafenib (REGO) plus FOLFIRINOX as frontline treatment in patients (pts) with RAS-mutated metastatic colorectal cancer (mCRC): A phase I/II, dose-escalation and dose-expansion study –* ***Investigator-Initiated Research (IIR)***
    - Abstract 3561; June 4, 9:00am EDT

- *REGOMAIN: A randomized, placebo-controlled, double-blinded, multicenter, comparative phase II study of the efficacy of regorafenib as maintenance treatment in patients (pts) with high-grade bone sarcomas (HGBS) at diagnosis or relapse and without complete remission after standard treatment –* ***Investigator-Initiated Research (IIR); Trial in Progress (TiP)***
    - Abstract TPS11585; June 5, 9:00am EDT
- *Activity of regorafenib in patients with non-adipocytic soft tissue sarcoma (NASTS): Evaluation of heterogeneity of treatment effect on the updated analysis of pooled cohorts –* ***Investigator-Initiated Research (IIR)***
    - Abstract 11555; June 5, 9:00am EDT

Sorafenib

- *Deficit Accumulation Frailty Index (DAFI) scores and acute myeloid leukemia outcomes –* ***Investigator-Initiated Research (IIR)***
    - Abstract 12040; June 4, 2:15pm EDT

About Oncology 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 innovative medicines that help improve and extend the lives of people living with cancer. The oncology franchise at Bayer includes six marketed products across various indications and several compounds in different stages of clinical development. Bayer focuses its research activities on first-in-class innovations across the following scientific platforms: Precision Molecular Oncology, Targeted Alpha Therapies, and Immuno-Oncology. Across the areas of focus, we have several prostate cancer treatments on the market or in development, with the goal of extending survival while limiting side effects of treatment throughout the different stages of the disease. Another key focus at Bayer is on innovative precision oncology treatments, with an approved TRK inhibitor exclusively designed to treat tumors that have an *NTRK* gene fusion, the oncogenic driver of tumor growth and spread. The company's approach to research 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 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 2021, the Group employed around 100,000 people and had sales of 44.1 billion euros. R&D expenses before special items amounted to 5.3 billion euros. For more information, go to www.bayer.com.

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