Bayer presents new data across oncology portfolio at the 2023 ASCO Annual Meeting

- Bayer continues to focus on advancing prostate cancer care from early to metastatic stage with darolutamide data in non-metastatic castration-resistant prostate cancer (nmCRPC) and metastatic hormone-sensitive prostate cancer (mHSPC), and radium-223 dichloride data in metastatic castration-resistant prostate cancer (mCRPC)
- Confirming Bayer’s investment in Precision Oncology, larotrectinib data presented at ASCO demonstrate long-term efficacy and safety in patients with tropomyosin receptor kinase (TRK) fusion lung and thyroid cancer, in addition to data from investigator-initiated research in pediatric patients with newly diagnosed infantile fibrosarcoma (IFS)

Abstracts: 5097, TPS5112, TPS5111, 5050, 3141, 9056, 6091, 10008, 2502, 7555, 6611

Berlin, May 25, 2023 – Bayer presents new data from across its oncology research and development programs at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting taking place between June 2-6, 2023. These presentations continue to underscore Bayer’s commitment to focus on approaches with the potential to transform the lives of people affected by cancer through science and innovation.

Prostate cancer remains a key area of focus at Bayer. Data featuring darolutamide and radium-223 dichloride will be presented during ASCO. Darolutamide data includes results from the DEAR trial evaluating real-world evidence (RWE) of darolutamide, enzalutamide and apalutamide in patients with non-metastatic castration-resistant prostate cancer (nmCRPC). Furthermore, ARASEC, an ongoing U.S.-based open-label study evaluating darolutamide versus androgen deprivation therapy (ADT) as well as ARAMON, an ongoing randomized, open-label Phase II study comparing the effects of darolutamide versus enzalutamide monotherapy on serum testosterone levels in patients with hormone-
naïve prostate cancer, will be featured at the congress. Darolutamide is approved under
the brand name Nubeqa™ in more than 80 countries around the world for the treatment of
patients with nmCRPC, who are at high risk of developing metastatic disease. It is also
approved for the treatment of patients with mHSPC in 50 markets including the U.S.,
Japan, EU and China.

Real-world safety and effectiveness data from the REASSURE study involving patients
with metastatic castration-resistant prostate cancer (mCRPC) treated with radium-223
dichloride will also be presented. Radium-223 dichloride (Xofigo™) is indicated for the
treatment of patients with mCRPC, symptomatic bone metastases, and no known visceral
metastatic disease.

Updated results from NAVIGATE and SCOUT studies further support larotrectinib’s
existing clinical benefit in tropomyosin receptor kinase (TRK) fusion cancer across a
variety of tumor types and ages. Extended long-term efficacy and safety findings of
larotrectinib in adult patients with TRK fusion lung cancer and thyroid carcinoma (TC) will
be presented. Additionally, an oral presentation of Phase II investigator-initiated research
featuring pediatric patients with newly diagnosed infantile fibrosarcoma (IFS) treated with
larotrectinib will be presented. Larotrectinib, under the brand name VitraKvi™, is approved
in more than 40 countries, including the U.S. and China for pediatric and adult patients
with NTRK fusion-positive advanced or recurrent solid tumors.

Additional data featuring Bayer’s oncology pipeline will include an oral presentation on the
initial results from a first-in-human, Phase I study of immunomodulatory aryl hydrocarbon
receptor (AhR) inhibitor BAY2416964 in patients with advanced solid tumors. The six-year
safety and efficacy results from CHRONOS-1 study analyzing copanlisib in patients with
relapsed or refractory follicular lymphoma (FL) will also be presented. Copanlisib is
approved under the brand name Aliqopa™ in the U.S. for the treatment of patients with
relapsed follicular lymphoma who have received at least two prior systemic therapies.

Key data to be presented at the 2023 ASCO Annual Meeting are listed below:

**Darolutamide**
- Comparative real-world (RW) evidence on darolutamide (Daro), enzalutamide
  (Enza), and apalutamide (Apa) for patients (Pts) with non-metastatic castration-
  resistant prostate cancer (nmCRPC) in the United States: DEAR
- 3/5 -

- Abstract 5097; June 3, 8:00am CDT
  - Open-label study of darolutamide plus androgen-deprivation therapy (ADT) vs ADT in metastatic hormone-sensitive prostate cancer using an external control arm (ARASEC)
    o Abstract TPS5112; June 3, 8:00am CDT
  - A phase 2, randomized, open-label study comparing the effects of darolutamide versus enzalutamide monotherapy on serum testosterone levels in patients with hormone-naive prostate cancer: ARAMON study
    o Abstract TPS5111; June 3, 8:00am CDT

Radium-223 dichloride (RA-233)
  - Real-world safety and effectiveness of radium-223 (²²³Ra) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) treated in the U.S.: The non-interventional REASSURE study
    o Abstract 5050; June 3, 8:00am CDT

Larotrectinib
  - Larotrectinib long-term efficacy and safety in adult patients (pts) with tropomyosin receptor kinase (TRK) fusion cancer
    o Abstract 3141; June 3, 8:00am CDT
  - Long-term efficacy and safety of larotrectinib in patients with tropomyosin receptor kinase (TRK) fusion lung cancer
    o Abstract 9056; June 4, 8:00am CDT
  - Larotrectinib (laro) long-term efficacy and safety in patients (pts) with tropomyosin receptor kinase (TRK) fusion thyroid carcinoma (TC)
    o Abstract 6091; June 5, 1:15pm CDT
  - Phase 2 study of larotrectinib in children with newly diagnosed infantile fibrosarcoma (IFS): Children’s Oncology Group (COG) ADVL1823 cohort A
    o Abstract 10008; June 4, 12:09pm CDT

Pipeline
  - Initial results from a first-in-human, Phase I study of immunomodulatory aryl hydrocarbon receptor (AhR) inhibitor BAY2416964 in patients with advanced solid tumors
    o Abstract 2502; June 4, 9:57am CDT
- Six-year safety and efficacy results from the CHRONOS-1 study of the PI3K inhibitor copanlisib in patients with relapsed or refractory follicular lymphoma
  
  - Abstract 7555; June 5, 8:00am CDT

**Oncology RWE Non-product Related**

- Using real-world evidence (RWE) in regulatory decision making: A study of 6 oncology approvals with RWE included in the product label
  
  - Abstract 6611; June 3, 1:15pm CDT

**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 new 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 Radionuclide Therapies, and Next-Generation Immuno-Oncology. Across the areas of focus, we have several prostate cancer treatments on the market or in development advancing prostate cancer care from early to metastatic stage, 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 2022, the Group employed
around 101,000 people and had sales of 50.7 billion euros. R&D expenses before special items amounted to 6.2 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.