News Release

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Bayer unveils latest data from growing oncology portfolio at ESMO Congress 2023

- Bayer’s focus remains on advancing prostate cancer care with darolutamide, supported by additional ARASENS and ARAMIS trial data evaluating prostate-specific antigen (PSA) outcomes in metastatic hormone-sensitive prostate cancer (mHSPC) and composite measurement of health-related quality of life (HRQoL) and deterioration-free survival (DetFS) in patients with non-metastatic castration-resistant prostate cancer (nmCRPC), respectively
- New data from the REASSURE observational study evaluating the combination of radium-223 dichloride with enzalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC)
- Bayer will present new real-world evidence on the benefit of sequencing regorafenib earlier in refractory metastatic colorectal cancer (mCRC)
- Bayer will share new efficacy and safety data for larotrectinib in patients with tropomyosin receptor kinase (TRK) fusion cancer, alongside a pooled analysis from three clinical trials of patients with longer follow-up
- Bayer will present the first disclosure of clinical data from a first-in-human, Phase I trial of BAY 2927088, an oral, reversible, potent tyrosine kinase inhibitor (TKI) in patients with EGFR or HER2 mutant non-small cell lung cancer (NSCLC)


Berlin, October 12, 2023 – Bayer will present new data from across its oncology programs at the upcoming European Society for Medical Oncology (ESMO) Congress, taking place in Madrid, Spain, from October 20-24, 2023. The breadth of new data showcases Bayer's ongoing commitment to supporting more patients living with cancer by prioritizing research and development that address the most pressing unmet medical needs.
Bayer continues to focus on advancing prostate cancer care from early to metastatic stages of the disease through the development of innovative treatments that aim to extend survival, delay disease progression, and enable patients to continue doing the things they love. Darolutamide data includes further results from the Phase III ARASENS trial which evaluates PSA outcomes with darolutamide and androgen deprivation therapy plus docetaxel by disease volume in mHSPC. In addition, Bayer will present new data on the effect of darolutamide on HRQoL and DetFS in patients with nmCRPC from the Phase III ARAMIS trial. Darolutamide is approved under the brand name Nubeqa™ in more than 80 countries around the world for the treatment of patients with nmCRPC. It is also approved for the treatment of patients with mHSPC in over 70 markets including the U.S., Japan, EU, and China.

Bayer will also present new data from the REASSURE observational study evaluating the clinical outcomes of patients with mCRPC who received combined or layered treatment with radium-223 dichloride and enzalutamide. Radium-223 dichloride, under the brand name Xofigo™, is indicated for the treatment of patients with mCRPC, symptomatic bone metastases and no known visceral metastatic disease in more than 50 countries.

Bayer also remains committed to gastrointestinal cancer care. New real-world data will be presented evaluating sequential treatment with regorafenib and trifluridine/tipiracil ± bevacizumab in patients with refractory mCRC. Regorafenib is approved under the brand name Stivarga™ in more than 100 countries for certain types of colorectal cancer, gastrointestinal stromal tumor and liver cancer.

As part of Bayer’s focus in precision oncology, Bayer will highlight the latest efficacy and safety data of larotrectinib, including results in patients with TRK fusion cancer treated with larotrectinib as first-line treatment, and data from a pooled analysis from three clinical trials (NCT02576431, NCT02122913, NCT02637687) of patients with longer follow-up. 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 neurotrophic tyrosine receptor kinase fusion-positive solid tumors.

Bayer will also present the latest data from its growing precision oncology pipeline, including the first disclosure of clinical data from a first-in-human, Phase I trial of
BAY 2927088, an oral, reversible, potent TKI in patients with EGFR or HER2 mutant NSCLC.

Details on presentations from Bayer at the 2023 ESMO Congress are listed below:

**Darolutamide**
- *Prostate-specific antigen (PSA) outcomes with darolutamide (DARO), androgen-deprivation therapy (ADT) and docetaxel (DOC) in patients (pts) with high- and low-volume metastatic hormone-sensitive prostate cancer (mHSPC) in ARASENS*
  - Poster: 1784P; October 22
- *Health-related quality of life (HRQoL) deterioration-free survival (DetFS) by prostate-specific antigen (PSA) decline in darolutamide (DARO)-treated patients with nonmetastatic castration-resistant prostate cancer (nmCRPC) from ARAMIS*
  - Poster: 1781P; October 22

**Radium-223**
- *Combination treatment with radium-223 (223Ra) and enzalutamide (enza) in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC) in the REASSURE study*
  - Poster: 1816P; October 22

**Regorafenib**
- *Sequential treatment with regorafenib (REG) and trifluridine/tipiracil (TAS) ± bevacizumab (Bev) in refractory metastatic colorectal cancer (mCRC) in community clinical practice in the USA*
  - Poster: 616P; October 22

**Larotrectinib**
- *Efficacy and safety of larotrectinib (laro) as first-line treatment for patients (pts) with tropomyosin receptor kinase (TRK) fusion cancer*
  - Poster: 667P; October 23
- *Efficacy and Safety of Larotrectinib in a Pooled Analysis of Patients (Pts) with Tropomyosin Receptor Kinase (TRK) Fusion Cancer*
  - Poster: 668P; October 23
Pipeline
- Early evidence of efficacy in patients (pts) with non-small cell lung cancer (NSCLC) with HER2 exon20 insertion (ex20ins) mutations treated in a Phase I study with BAY 2927088
  - Mini Oral Session: 1320MO; October 22

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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