



Bayer AG
Communications
51368 Leverkusen
Germany
Phone +49 214 30-1
www.bayer.com/en/media

News Release

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Bayer to present extensive new data from its oncology portfolio at ESMO 2024

- Bayer will reveal late-breaking data from the Phase III ARANOTE trial in metastatic hormone-sensitive prostate cancer for darolutamide
 - Late-breaking data from the PEACE-III study of the first and only approved targeted alpha therapy radium-223 dichloride in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer will also be presented
 - As part of Bayer's broader commitment to innovate in the field of difficult-to-treat cancers, new data on larotrectinib and an update on BAY 2927088 will be presented at the congress
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Abstracts: LBA68, LBA1, 1629P, 1395TiP, 628P

Berlin, September 5, 2024 – Bayer will present new oncology data at the upcoming European Society for Medical Oncology (ESMO) Congress, taking place in Barcelona, Spain, from 13-17 September 2024.

Prostate cancer is a key focus area for Bayer, with late-breaking data to be revealed on darolutamide and radium-223. The company's ambition to advance prostate cancer care includes the development and delivery of innovative treatments that delay disease progression and extend survival across different stages of the disease. These additional treatment options could enable physicians to tailor treatment plans based on a patient's individual needs, while maintaining their daily living.

As part of its robust development program for darolutamide, Bayer will present a late-breaking abstract on the ARANOTE study in an oral session providing a comprehensive analysis from this third pivotal Phase III trial that investigated the efficacy and safety of darolutamide plus androgen-deprivation therapy (ADT) in patients with metastatic

hormone-sensitive prostate cancer (mHSPC) versus ADT alone. Darolutamide is already approved under the brand name Nubeqa® in combination with ADT and docetaxel for the treatment of patients with mHSPC in over 80 markets including the U.S., Japan, EU, and China. It is also approved in more than 85 countries around the world for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC), who are at high risk of developing metastatic disease.

In the field of targeted radionuclide therapies, late-breaking data will be presented from the European Organisation for Research and Treatment of Cancer (EORTC) sponsored Phase III PEACE-III study in a “Presidential Symposium I: Practice-changing trials”. Bayer supports the study that compares enzalutamide to a combination of enzalutamide with radium-223 dichloride in patients with asymptomatic or mildly symptomatic metastatic castration-resistant prostate cancer (mCRPC). Radium-223 dichloride is approved under the brand name Xofigo® in more than 50 countries for the treatment of patients with mCRPC, who have symptomatic bone metastases and no known visceral metastatic disease.

In addition to the data from the SOHO-01 study to be unveiled at the 2024 World Conference on Lung Cancer (WCLC 2024), the study design of the recently started Phase III SOHO-02 trial, evaluating the effect of oral BAY 2927088, compared with standard of care, as first-line treatment for locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring HER2-activating mutations, will be presented. BAY 2927088 is an oral, small molecule tyrosine kinase inhibitor under development as a potential new targeted therapy for patients with NSCLC harboring HER2 activating mutations.

Bayer will also highlight updated analysis from the SCOUT and NAVIGATE studies evaluating the efficacy and safety of larotrectinib as a first-line treatment for children and adults with TRK fusion cancer, respectively. Larotrectinib, marketed under the brand name Vitrekvi®, is approved in more than 45 countries for pediatric and adult patients with neurotrophic TRK fusion-positive solid tumors, including the U.S. and China.

Details on selected abstracts from Bayer at the 2024 ESMO Congress are listed below:

Darolutamide

- *Efficacy and safety of darolutamide plus androgen-deprivation therapy (ADT) in patients with metastatic hormone-sensitive prostate cancer (mHSPC) from the phase 3 ARANOTE trial*

- o Abstract: LBA68; September 16, 2024. 10:15am – 11:45am CET

Radium-223 dichloride

- *A randomized multicenter open-label phase III trial comparing enzalutamide vs. a combination of radium-223 (223Ra) and enzalutamide in asymptomatic or mildly symptomatic patients with castration-resistant prostate cancer and bone metastases. Primary results of EORTC-1333/PEACE III*
 - o Abstract: LBA1; September 14, 2024. 16:30pm – 18:15pm CET
- *Lutetium-177–prostate-specific membrane antigen (177Lu-PSMA) therapy in patients with prior radium-223 (223Ra)*
 - o Abstract: 1629P; September 15, 2024.

BAY 2927088

- *A randomized phase III trial evaluating oral BAY 2927088, compared with standard of care, as first-line treatment of locally advanced or metastatic NSCLC harboring HER2-activating mutations (SOHO-02)*
 - o Abstract: 1395TiP; September 14, 2024.

Larotrectinib

- *Efficacy and safety of larotrectinib as first-line treatment for patients with TRK fusion cancer: an updated analysis*
 - o Abstract: 628P; September 14, 2024.

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 several marketed products across diverse indications and multiple compounds in different stages of clinical development. Bayer focuses its research activities on precision drug development. We have a wealth of expertise in areas including: Tumor Intrinsic Pathways, Targeted Radionuclide Therapies, and Next-Generation Immuno-Oncology. We are advancing prostate cancer treatment from early to metastatic stage, with the goal of extending survival while limiting side effects. Part of Bayer's focus on innovative precision oncology treatments, includes an approved TRK inhibitor exclusively designed to treat tumors that have an NTRK gene fusion, the oncogenic driver of tumor growth and spread.

About Bayer

Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. In line with its mission, "Health for all, Hunger for none," the company's 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 2023, the Group employed around 100,000 people and had sales of 47.6 billion euros. R&D expenses before special items amounted to 5.8 billion euros. For more information, go to www.bayer.com.

Contact for media inquiries:

Malena Johannes, phone +49 30 2215 41591

Email: malena.johannes@bayer.com

Silvia Grosso, phone +1 973 270 6828

Email: silvia.grosso@bayer.com

Find more information at <https://pharma.bayer.com/>

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