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News Release

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Darolutamide meets primary endpoint in Phase III ARANOTE trial in men with metastatic hormone-sensitive prostate cancer

- ARANOTE trial meets primary endpoint, significantly increasing radiological progression-free survival (rPFS) with darolutamide + androgen deprivation therapy (ADT) compared to placebo plus ADT
- Safety analysis shows darolutamide plus ADT to be comparable to placebo plus ADT, reconfirming the established tolerability profile of darolutamide as observed in the ARAMIS and ARASENS trials
- Darolutamide plus ADT now has positive data both with and without docetaxel based on two pivotal phase III studies in metastatic hormone-sensitive prostate cancer (mHSPC)
- Bayer plans to present the pivotal data at a forthcoming scientific congress and prepare for submission with health authorities globally to extend the indication of darolutamide

Berlin, July 17, 2024 – The Phase III ARANOTE trial, investigating darolutamide plus ADT in patients with metastatic hormone-sensitive prostate cancer (mHSPC), has met its primary endpoint of rPFS. Darolutamide plus ADT significantly increased rPFS compared to placebo plus ADT. The safety data were comparable between both treatment arms and reconfirm the established tolerability profile of darolutamide in advanced prostate cancer. Darolutamide is already approved under the brand name Nubeqa™ for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC), who are at high risk of developing metastatic disease, and patients with mHSPC (in combination with ADT and docetaxel).

“We are excited to share the positive results from this Phase III trial. Following potential regulatory approval, physicians can tailor treatment plans with or without docetaxel based on individual patient´s needs” said Christian Rommel, Ph.D., Head of Research and

Development at Bayer's Pharmaceuticals Division. "Today's results build on the established efficacy and tolerability profile for Nubeqa™. We are looking forward to future outcomes of our clinical development program investigating the compound across multiple prostate cancer stages and indications."

Detailed results of the ARANOTE trial are planned to be presented at a forthcoming scientific congress. Bayer plans to submit the data from the study to relevant health authorities globally to support expanded use of darolutamide in men with mHSPC. ARANOTE is part of a robust clinical development program investigating darolutamide across various stages of prostate cancer, which includes the Phase III ARASTEP trial evaluating darolutamide plus ADT versus ADT alone in hormone-sensitive high-risk biochemical recurrence (BCR) prostate cancer, who have no evidence of metastatic disease by conventional imaging and a positive PSMA PET/CT at baseline. Furthermore, darolutamide is also being investigated in the collaborative Phase III DASL-HiCaP (ANZUP1801) trial led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). The study evaluates darolutamide as an adjuvant treatment for localized prostate cancer with very high risk of recurrence.

About the ARANOTE Trial

The ARANOTE trial is a randomized, double-blind, placebo-controlled Phase III study designed to assess the efficacy and safety of darolutamide plus ADT in patients with mHSPC. 669 patients were randomized to receive 600mg of darolutamide twice daily or matching placebo in addition to ADT.

The primary endpoint of this study is rPFS, measured as time from randomization to date of first documented radiological progressive disease or death due to any cause, whichever occurs first. Secondary endpoints include overall survival (time to death from any cause), time to first castration-resistant event, time to initiation of subsequent anti-cancer therapy, time to prostate-specific antigen (PSA) progression, PSA undetectable rates, time to pain progression, and safety assessments.

About Metastatic Hormone-Sensitive Prostate Cancer

Prostate cancer is the second most common cancer in men and the fifth most common cause of cancer death in men worldwide.[1] In 2020, an estimated 1.4 million men were diagnosed with prostate cancer, and about 375,000 died from the disease worldwide.[2]

At the time of diagnosis, most men have localized prostate cancer, meaning their cancer is confined to the prostate gland and can be treated with curative surgery or radiotherapy. mHSPC is a stage in the disease where the cancer has spread outside of the prostate to other parts of the body. Up to 10% of men will present with mHSPC when first diagnosed.[3,4,5] For patients with mHSPC, ADT is the cornerstone of treatment, often in combination with chemotherapy docetaxel and/or an androgen receptor inhibitor (ARi). Despite treatment, most men with mHSPC will eventually progress to castration-resistant prostate cancer (CRPC), a condition with limited survival.

About darolutamide (Nubeqa™)

Darolutamide is an oral ARi with a distinct chemical structure that binds to the androgen receptor with high affinity and exhibits strong antagonistic activity, thereby inhibiting the receptor function and the growth of prostate cancer cells. The low potential for blood-brain barrier penetration for darolutamide is supported by preclinical models and neuroimaging data in healthy humans. This is also supported by the overall low incidence of central nervous system (CNS)-related adverse events (AEs) compared to placebo as seen in the ARAMIS Phase III trial and the maintained verbal learning and memory observed in the darolutamide arm of the Phase II ODENZA trial.

Darolutamide is approved under the brand name Nubeqa™ 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. It is also approved 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. The product is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

About Prostate Cancer 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. Prostate cancer is the second most commonly diagnosed cancer in men[1] and a key area of focus for Bayer. The company's franchise includes two products on the market (Nubeqa™ and Xofigo™) and several compounds in development. Bayer is focused on addressing the unique needs of patients with prostate cancer, providing treatments that extend their lives

throughout the different stages of the disease and allowing them to continue with their everyday activities, so that patients can live longer, better lives.

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.

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