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News Release

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Phase III trial with darolutamide in combination with docetaxel and androgen deprivation therapy meets primary endpoint of significantly increasing overall survival in patients with metastatic hormone-sensitive prostate cancer

- ARASENS trial demonstrates an increase in overall survival evaluating darolutamide in combination with docetaxel and androgen deprivation therapy (ADT) compared to docetaxel and ADT, a standard of care in metastatic hormone-sensitive prostate cancer (mHSPC)
- Bayer plans to present these pivotal data at a forthcoming scientific congress and to discuss them with health authorities
- ARASENS is part of broad development program for darolutamide which includes another ongoing Phase III trial in mHSPC, ARANOTE, evaluating darolutamide plus ADT

Berlin, December 3, 2021 – The Phase III ARASENS trial investigating the use of the oral androgen receptor inhibitor (ARi) Nubeqa™ (darolutamide) in metastatic hormone-sensitive prostate cancer (mHSPC) has met its primary endpoint. In the ARASENS trial, darolutamide in combination with docetaxel and androgen deprivation therapy (ADT) significantly increased overall survival (OS) compared to docetaxel and ADT. The overall incidence of reported adverse events was similar between treatment arms. Detailed results of the study are planned to be presented at an upcoming scientific congress. The ARASENS trial is the only Phase III randomized, multi-center, double-blind trial which was prospectively designed to evaluate the efficacy and safety of a combination of an ARi with docetaxel and ADT compared to docetaxel and ADT in patients with mHSPC.

Darolutamide is approved in multiple markets around the world, including the U.S., the European Union (EU), Japan and China, 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. Filings in other regions are underway or planned. The product is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

“For patients with mHSPC, there remains a significant need for new therapeutic approaches that improve treatment outcomes. ARASENS was prospectively designed to investigate whether combining darolutamide with docetaxel and ADT could lead to an increase in overall survival for men with mHSPC,” said Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division. “We are especially grateful to the patients and investigators for participating in this important trial and look forward to presenting the full results at an upcoming meeting.”

Bayer plans to discuss the data from ARASENS with health authorities worldwide regarding the submission for marketing authorization in this indication.

About the ARASENS Trial

The ARASENS trial is a randomized, Phase III, multi-center, double-blind, placebo-controlled trial which was prospectively designed to investigate the safety and efficacy of oral darolutamide, an androgen receptor inhibitor (ARi), in combination with the chemotherapy docetaxel and androgen deprivation therapy (ADT) in patients with metastatic hormone-sensitive prostate cancer (mHSPC). 1,306 newly diagnosed patients were randomized in a 1:1 ratio to receive 600 mg of darolutamide twice a day or matching placebo, in addition to docetaxel and standard ADT.

The primary endpoint of this trial is overall survival (OS). Secondary endpoints include time to castration-resistant prostate cancer (CRPC), time to initiation of subsequent anticancer therapy, time to first symptomatic skeletal event (SSE), time to pain progression, all measured at 12-week intervals, as well as adverse events as a measure of safety and tolerability.

About Metastatic Hormone-Sensitive Prostate Cancer

Prostate cancer is the second most commonly diagnosed malignancy in men worldwide. In 2020, an estimated 1.4 million men were diagnosed with prostate cancer, and about 375,000 died from the disease worldwide.[1]

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. Upon relapse when the disease will metastasize or spread, androgen deprivation therapy (ADT) is the cornerstone of treatment for this hormone-sensitive disease. Approximately 5% of men will already suffer from prostate cancer with distant metastases when first diagnosed. Men with metastatic hormone-sensitive prostate cancer (mHSPC) will start their treatment with hormone therapy, such as ADT, androgen receptor inhibitor (ARi) plus ADT or a combination of the chemotherapy docetaxel and ADT. Despite this treatment, most men with mHSPC will eventually progress to castration-resistant prostate cancer (CRPC), a condition with limited survival.

About Nubeqa™ (darolutamide)

Darolutamide is an oral androgen receptor inhibitor (ARi) with a distinct chemical structure that binds to the 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. A low blood-brain barrier penetration would explain 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 significant improvement in verbal memory in the Phase II ODENZA trial. The product is approved under the brand name Nubeqa™ in several markets 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. The compound is also being investigated in further studies across various stages of prostate cancer, including another Phase III trial in metastatic hormone-sensitive prostate cancer (mHSPC) (ARANOTE) as well as a Phase III trial evaluating darolutamide as an adjuvant treatment for localized prostate cancer with very high risk of recurrence (DASL-HiCaP). Information about these trials can be found at www.clinicaltrials.gov.

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, including a unique approach of

advancing targeted alpha therapies. Bayer is focused on addressing the unique needs of prostate cancer patients, providing treatments that extend their lives throughout the different stages of the disease and allowing them to continue their everyday activities, so that they 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. Its products and services are designed to help people and planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to drive sustainable development and generate 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 2020, the Group employed around 100,000 people and had sales of 41.4 billion euros. R&D expenses before special items amounted to 4.9 billion euros. For more information, go to www.bayer.com.

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Reference

1. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries. *CA: A Cancer Journal for Clinicians.* https://acsjournals.onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21660. Accessed October 2021.