



Bayer AG
Communications
51368 Leverkusen
Germany
Tel. +49 214 30-1
media.bayer.com

News Release

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Bayer and Orion expand development program for darolutamide in prostate cancer

- Phase III study ARANOTE to be initiated in metastatic hormone-sensitive prostate cancer (mHSPC) assessing the novel androgen-receptor antagonist in combination with standard androgen deprivation therapy
 - Start of patient enrollment expected by the end of Q1 2021
 - Study adds to the robust development program for NUBEQA, exploring an opportunity to help even more patients with prostate cancer
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Berlin, February 8, 2021 – Bayer and Orion Corporation are expanding the global clinical development program for the oral androgen receptor inhibitor (ARi) Nubeqa™ (darolutamide) in the area of prostate cancer. A new Phase III study ARANOTE will evaluate the compound in addition to androgen deprivation therapy (ADT) versus placebo plus ADT in men with metastatic hormone-sensitive prostate cancer (mHSPC). The study adds to the robust development program for the compound, including the Phase III study ARASENS, which investigates darolutamide in a triple combination with ADT and docetaxel compared to docetaxel and ADT alone in men with mHSPC.

“Darolutamide has already shown in men with non-metastatic castration-resistant prostate cancer (nmCRPC) that it extends life with a favorable safety profile allowing men to continue their lifestyle with only minimal disruption” said Dr. Scott Z. Fields, Senior Vice President and Head of Oncology Development, Bayer. “Given the encouraging results that we have seen with the compound so far, it is important that we also evaluate the potential of darolutamide in other stages of the disease to offer men with mHSPC a new treatment option that is effective and addresses the challenge of bothersome side effects.”

Darolutamide is approved in several markets around the world, including the U.S., the European Union (EU), Brazil, Canada, Japan and China, for the treatment of patients with

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.

About the ARANOTE trial

The ARANOTE trial is a randomized, double-blind, placebo-controlled Phase III study of darolutamide in addition to androgen deprivation therapy (ADT) versus placebo plus ADT in men with metastatic hormone-sensitive prostate cancer (mHSPC). The primary endpoint of this study is radiological progression-free survival (rPFS), as measured as the time from the date of randomization to the date of first documentation of radiological progressive disease or death due to any cause, whichever occurs first. The trial is expected to enroll about 555 men. Bayer anticipates that first patients will be enrolled to the study by end of Q1 2021.

About Metastatic Hormone-Sensitive Prostate Cancer

Prostate cancer is the second most commonly diagnosed malignancy in men worldwide. In 2018, an estimated 1.2 million men were diagnosed with prostate cancer, and about 358,000 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 five percent of men will already suffer from prostate cancer with distant metastases when first diagnosed. Men with metastatic hormone-sensitive prostate cancer (HSPC) will start their treatment with hormone therapy, such as ADT, ARi plus ADT or a combination of the chemotherapy docetaxel and ADT. Despite this first-line treatment, most men with metastatic HSPC will eventually progress to castration-resistant prostate cancer (CRPC), which can impact survival and quality of life.

About Nubeqa™ (darolutamide)

Darolutamide is approved under the brand name Nubeqa™ for the treatment of men with non-metastatic castration-resistant prostate cancer (nmCRPC), who are at high risk of developing metastatic disease.

Nubeqa 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 compound is also being investigated in a Phase III study in metastatic hormone-sensitive prostate cancer (ARASENS). 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 men¹ 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 benefit people by supporting efforts to overcome the major challenges presented by a growing and aging global population. At the same time, the Group aims to increase its earning power and create value through innovation and growth. Bayer is committed to the principles of sustainable development, and the Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2019, the Group employed around 104,000 people and had sales of 43.5 billion euros. Capital expenditures amounted to 2.9 billion euros, R&D expenses to 5.3 billion euros. For more information, go to www.bayer.com.

Contact:

Malena Johannes, phone +49 30 468-14079

Email: malena.johannes@bayer.com

Contact for investor inquiries:

Bayer Investor Relations Team, phone +49 214 30-72704

Email: ir@bayer.com

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¹ GLOBOCAN 2018: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2018. CA: A Cancer Journal for Clinicians. <https://onlinelibrary.wiley.com/doi/epdf/10.3322/caac.21492>.