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

News Release

Not intended for U.S. and UK Media

Bayer receives positive CHMP opinion for darolutamide as a new treatment for men with non-metastatic castration-resistant prostate cancer

- CHMP opinion is based on Phase III ARAMIS trial data evaluating the efficacy and safety of darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT
- Final decision from the European Commission is anticipated within the coming months

Berlin, January 31, 2020 –The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended darolutamide, a non-steroidal androgen receptor inhibitor (ARi), for marketing authorization in the European Union (EU). The compound, which is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company, is recommended for the treatment of men with non-metastatic castration-resistant prostate cancer (nmCRPC), who are at high risk of developing metastatic disease. The final decision from the European Commission on the marketing authorization is expected in the coming months. The compound is already approved in the U.S., Brazil and Japan and filings in other regions are underway or planned. Bayer is responsible for global commercialization, with a co-promotion of Bayer and Orion Corporation in certain European markets, e.g. in France, Germany, Italy, Spain, the UK, Scandinavia and Finland.

The CHMP recommendation is based on the results of the Phase III ARAMIS trial evaluating darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT, which demonstrated a highly significant improvement in the primary efficacy endpoint of metastasis-free survival (MFS) of darolutamide plus ADT, with a median 40.4 months, versus 18.4 months for placebo plus ADT ($p<0.0001$), and a favorable safety profile.

“For patients with nmCRPC who typically have asymptomatic disease, it is critical that they have treatment options that delay metastases, and that also can limit the burdensome side effects of therapy”, said Dr. Scott Z. Fields, Senior Vice President and Head of Oncology Development at Bayer. “This positive CHMP opinion for darolutamide marks a significant step forward in delivering a potential new therapeutic option that has the potential to both extend MFS in nmCRPC and limit the impact of side effects, meeting an unmet medical need.”

“The positive CHMP opinion takes us one step closer to bringing this new therapeutic option to men with nmCRPC in the EU and demonstrates our ongoing commitment to delivering innovative medicines. We are looking forward to the co-promotion with Bayer to support patients with prostate cancer and their healthcare professionals”, said Satu Ahomäki, Senior Vice President, Commercial Operations of Orion Corporation.

Prostate cancer that is confined to the prostate region and is treated with ADT but keeps progressing, even when the amount of testosterone is reduced to very low levels in the body, is known as nmCRPC. In Europe over 67,000 men are estimated to have a CRPC diagnosis, based on 2018 prostate cancer incidence numbers. About one-third of men with nmCRPC go on to develop metastases within two years.

In the ARAMIS trial, overall survival (OS) and time to pain progression were additional secondary efficacy endpoints. At the time of final MFS analysis, a positive trend in OS was observed; OS data were not yet mature. The MFS result was additionally supported by a delay in time to pain progression as compared to placebo plus ADT. All other secondary endpoints, time to cytotoxic chemotherapy, and time to a symptomatic skeletal event (SSE), also demonstrated a benefit in favor of darolutamide at the time of final MFS analysis.

The most frequent adverse reactions in the darolutamide plus ADT arm, that occurred with an absolute increase in frequency of ≥2% compared to placebo plus ADT, were fatigue/asthenic conditions (16% vs. 11%), pain in extremity (6% vs. 3%), and rash (3% vs. 1%). Discontinuation due to adverse events occurred in 9% of patients in both arms of the study.

About the ARAMIS trial

The ARAMIS trial is a randomized, Phase III, multi-center, double-blind, placebo-controlled trial evaluating the safety and efficacy of oral darolutamide in patients with nmCRPC who are currently being treated with ADT and are at high risk for developing metastatic disease. In the clinical study, 1,509 patients were randomized in a 2:1 ratio to receive 600 mg of darolutamide orally twice daily or placebo along with ADT. Patients with a history of seizure were allowed in the study.

About darolutamide

Darolutamide is an 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.

The product has been approved in the U.S., Brazil and Japan under the brand name Nubeqa®. It has not been approved by the European Medicines Agency.

About castration-resistant prostate cancer (CRPC)

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. Prostate cancer is the fifth leading cause of death from cancer in men. Prostate cancer results from the abnormal proliferation of cells within the prostate gland, which is part of a man’s reproductive system. It mainly affects men over the age of 50, and the risk increases with age.

Treatment options range from surgery to radiation treatment to therapy using hormone-receptor antagonists, i.e., substances that stop the formation of testosterone or prevent its effect at the target location. However, in nearly all cases, the cancer eventually becomes resistant to conventional hormone therapy.

CRPC is an advanced form of the disease where the cancer keeps progressing despite ADT treatment, even when the amount of testosterone is reduced to very low levels in the body. In men with progressive nmCRPC, a rapid PSA doubling time has been consistently associated with reduced time to first metastasis and death.

About Oncology at Bayer

Bayer is committed to delivering science for a better life by advancing a portfolio of innovative treatments. The oncology franchise at Bayer now expands to six marketed products and several other assets in various stages of clinical development. Together, these products reflect the company's approach to research, which 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 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 2018, the Group employed around 117,000 people and had sales of 39.6 billion euros. Capital expenditures amounted to 2.6 billion euros, R&D expenses to 5.2 billion euros. For more information, go to www.bayer.com.

Contact:
Anna Koch, phone +49 30 468-15942
Email: anna.koch@bayer.com

Find more information at www.pharma.bayer.com
Our online press service is just a click away: media.bayer.com
Follow us on Facebook: http://www.facebook.com/pharma.bayer
Follow us on Twitter: @BayerPharma

ko (2020-0032E)