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Investor News

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Phase III trial of darolutamide in patients with non-metastatic castration-resistant prostate cancer meets primary endpoint

The safety and tolerability observed in the trial were consistent with previously published data on darolutamide

Leverkusen, Germany, October 24, 2018 – The Phase III ARAMIS (**A**ndrogen **R**eceptor inhibiting **A**gent for **M**etastatIc-free **S**urvival) trial that investigated darolutamide in men with non-metastatic castration-resistant prostate cancer (nmCRPC) met its primary endpoint. Darolutamide significantly extended metastasis-free survival (MFS) compared to placebo. The safety profile and the tolerability of darolutamide observed in the ARAMIS trial were consistent with previously published data on darolutamide. ARAMIS is a randomized, multi-center, double-blind, placebo-controlled trial in patients with nmCRPC. Darolutamide is an investigational, oral androgen receptor (AR) antagonist developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

“Despite recent advances in nmCRPC, there remains a high unmet need for additional treatment options that delay the time to metastases with a manageable safety profile,” said Scott Fields, MD, senior vice president and head of Oncology Development at Bayer’s Pharmaceutical Division. “We are encouraged by the results of the ARAMIS trial and look forward to presenting the full data at an upcoming scientific meeting.”

Bayer plans to discuss the data from the ARAMIS trial with health authorities regarding the submission of marketing authorization application. Bayer has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for darolutamide in men with nmCRPC.

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 androgen deprivation therapy (ADT) as standard of care and are at risk for developing metastatic disease. More than 1,500 patients were randomized in a 2:1 ratio to receive 600 mg of darolutamide twice a day or placebo.

The primary endpoint of this trial is metastasis-free survival (MFS) defined as time between randomization and evidence of metastasis or death from any cause. The secondary objectives of this trial are overall survival (OS), time to first symptomatic skeletal event (SSE), time to initiation of first cytotoxic chemotherapy, time to pain progression and characterization of the safety and tolerability of darolutamide.

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 will be diagnosed with prostate cancer, and about 358,000 will die 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 will become resistant to conventional hormone therapy.

CRPC is an advanced form of the disease where the cancer keeps progressing even when the amount of testosterone is reduced to very low levels in the body. The field of treatment options for castration-resistant patients is evolving rapidly, but until recently, there have been no effective treatment options for CRPC patients who have rising Prostate-Specific Antigen (PSA) levels during ADT and no detectable metastases. In men with progressive nmCRPC, a short PSA doubling time has been consistently associated with reduced time to first metastasis and death.

About Darolutamide
Darolutamide is a non-steroidal androgen receptor antagonist 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. Darolutamide has shown promising activity in Phase 1/2 studies in patients with mCRPC. A Phase 3 study in metastatic hormone-sensitive prostate cancer (ARASENS) is ongoing. Information about these trials can be found at www.clinicaltrials.gov.

Darolutamide is not approved by the U.S. FDA, the European Medicines Agency or any other health authority.

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 includes four marketed products and several other compounds 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 agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2017, the Group employed around 99,800 people and had sales of EUR 35.0 billion. Capital expenditures amounted to EUR 2.4 billion, R&D expenses to EUR 4.5 billion. For more information, go to www.bayer.com.

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