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News Release

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New ARAMIS Phase III data to be presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program

Nubeqa™ (darolutamide) significantly improved overall survival with a favorable safety profile in men with non-metastatic prostate cancer

- Darolutamide significantly reduced risk of death by 31 percent (HR=0.69, 95% CI 0.53-0.88; p=0.003) in men with non-metastatic castration-resistant prostate cancer (nmCRPC)
- Darolutamide significantly delayed the time to pain progression, time to first initiation of cytotoxic chemotherapy, and time to first symptomatic skeletal event (SSE)
- Darolutamide continues to demonstrate a favorable safety profile, with no new safety signals observed, even with a longer treatment duration, allowing men with nmCRPC to maintain their active lifestyle
- ARAMIS data will be presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program on Friday, May 29, and will be available on the ASCO website

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Abstract: 5514

Berlin, May 13, 2020 – Darolutamide (Nubeqa™) is shown to significantly improve overall survival (OS) and significantly delay the onset of cancer-associated symptoms, while minimizing the toxicity associated with treating men with non-metastatic castration-resistant prostate cancer (nmCRPC). These data from the pre-specified final OS analysis of the Phase III ARAMIS trial will be presented at the American Society of Clinical Oncology (ASCO) 2020 Virtual Scientific Program, which takes place from May 29-31, 2020.

Previously published results from the ARAMIS trial demonstrated a highly significant improvement in the primary efficacy endpoint of metastasis-free survival (MFS), with a

median of 40.4 months for darolutamide plus androgen deprivation therapy (ADT) compared to 18.4 months for placebo plus ADT ($p<0.001$); however, OS data were not yet mature at the time of the MFS analysis.

“Men with nmCRPC typically do not have cancer symptoms. In selecting a treatment for these patients, my goal as a clinician is to improve their overall survival while limiting side effects and drug interactions,” said Karim Fizazi, M.D., Ph.D., Professor of Medicine at the Institut Gustave Roussy, Villejuif, France. “These data add to the growing evidence for darolutamide as an effective treatment option with a favorable safety profile that extends patients’ lives and delays cancer symptoms and morbidities, without disrupting their daily activities.”

Final OS Analysis Presented at ASCO Virtual Scientific Program

Men receiving darolutamide plus ADT demonstrated a significant improvement in OS compared to placebo plus ADT, with a 31 percent reduction in risk of death (HR=0.69, 95% CI 0.53-0.88; p=0.003).

Darolutamide has a distinct chemical structure and inhibits the growth of prostate cancer cells while limiting the burden of side effects on patients’ everyday lives. With extended follow-up, darolutamide’s safety profile remains favorable, allowing men with nmCRPC to continue their daily lives without disruption. Consistent with the previously reported primary analysis results, darolutamide plus ADT showed a favorable tolerability confirmed by a longer-term safety analysis compared to ADT alone, without clinically relevant increases in rates of hypertension, falls or central nervous system (CNS) effects. In the follow-up analysis of secondary endpoints, all secondary endpoints were statistically significant. Darolutamide plus ADT significantly delayed time to pain progression, time to first initiation of cytotoxic chemotherapy and time to first symptomatic skeletal event (SSE) versus placebo plus ADT.

Under the brand name Nubeqa™, darolutamide is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company, and indicated for the treatment of men with nmCRPC, who are at high risk of developing metastatic disease. The approvals of Nubeqa in the European Union (EU), U.S., Australia, Brazil, Canada, and Japan are based on the pivotal Phase III ARAMIS trial data evaluating the efficacy and safety of darolutamide plus ADT compared to placebo plus ADT.

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 Nubeqa™ (darolutamide)

Darolutamide was approved in March 2020 in the European Union (EU) 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 has also received regulatory approval in the U.S., Australia, Brazil, Canada as well as Japan, and filings in other regions are underway or planned.

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 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.

Prostate cancer that is confined to the prostate region which is treated with ADT but keeps progressing without showing metastases, even when the amount of testosterone is reduced to very low levels in the body, is known as nmCRPC. In men with progressive nmCRPC, a rapid prostate specific antigen (PSA) doubling time has been consistently associated with reduced time to first metastasis and death. About one-third of men with nmCRPC go on to develop metastases within two years.

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 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.

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Forward-Looking Statements
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