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News Release

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Bayer receives approval for Nubeqa™ in China for the treatment of men with non-metastatic castration-resistant prostate cancer (nmCRPC)

Berlin, February 3, 2021 – The Chinese National Medical Products Administration (NMPA) has approved Nubeqa™ (darolutamide) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. Nubeqa has already received regulatory approval in several other markets around the world, including the U.S., the European Union (EU), Brazil, Canada and Japan. Filings in other regions are underway or planned. Nubeqa is developed jointly by Bayer and Orion Corporation, a globally operating Finnish pharmaceutical company.

“We are pleased that Nubeqa, a differentiated treatment option that extends life while preserving quality of life for men with nmCRPC, will now be available for patients in China,” said Scott Z. Fields, M.D., senior vice president and head of Oncology Development of Bayer AG's Pharmaceutical Division. “Following this and the recent approval of Xofigo® (Radium-223 dichloride) for patients with castration-resistant prostate cancer (CRPC) and symptomatic bone metastasis, we can now bring two therapeutic options to the increasing number of men living with prostate cancer in China to address their multiple medical needs across disease stages.”

This approval in China is based on the Phase III ARAMIS trial evaluating the efficacy and safety of darolutamide plus androgen deprivation therapy (ADT) compared to placebo plus ADT, showing a statistically significant improvement in the primary efficacy endpoint of metastasis-free survival (MFS), with a median of 40.4 months for darolutamide plus ADT versus 18.4 months for placebo plus ADT (HR=0.41, 95% CI 0.34-0.50; P<0.001). The final overall survival (OS) analysis published in *The New England Journal of Medicine* showed 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 demonstrated favorable safety and tolerability, even with longer follow-up, with discontinuation of treatment due to adverse events (AEs) occurring in 9 percent of patients in both arms of the study. Results from the ARAMIS trial also confirm the low potential for central nervous system (CNS) side effects, such as falls, mental impairment and cognitive impairment, expected with darolutamide plus ADT.[1-3]

“Prostate cancer is the sixth most common cancer in men in China,”[4] said Prof. Huang Jian, SUN YAT-SEN Memorial Hospital, SUN YAT-SEN University. “Prostate cancer that is treated with ADT but progresses as evidenced by rising prostatic-specific antigen (PSA) levels, even when the amount of testosterone is reduced to very low levels in the body, and without radiographic evidence of distant metastasis, is known as nmCRPC. About one-third of men with nmCRPC receiving ADT alone go on to develop metastases within two years,[5,6] so early diagnosis and timely intervention at this stage is critical. As these men typically have no symptoms and are leading active lives, it is important to have treatment options that delay disease progression and prolong their overall survival (OS), while minimizing burdensome treatment side effects, so they can maintain their lifestyle with little disruption.”

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 the ARAMIS trial

The ARAMIS trial was 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 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[7] 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.

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References

[1] Fizazi K. et al. Nonmetastatic, Castration-Resistant Prostate Cancer and Survival with Darolutamide. *N Engl J Med* 2020; 383:1040-1049.

[2] Zurth, Christian; Sandmann, Steffen; Trummel, Dagmar, et al. Higher blood–brain barrier penetration of [14C]apalutamide and [14C]enzalutamide compared to [14C]Darolutamide in rats using whole-body autoradiography. ASCO GU. Abstract 156. https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.7_suppl.156.

[3] Williams, Steven; Mazibuko, Ndaba; O'Daly, Owen, et al. Analysis of cerebral blood flow (CBF) in regions relevant to cognitive function with enzalutamide ENZA) compared to darolutamide (DARO) and placebo (PBO) in healthy volunteers. ASCO GU. Abstract 326. https://ascopubs.org/doi/abs/10.1200/JCO.2020.38.6_suppl.326.

[4] Rongshou, Z., et al. Analysis of the prevalence of malignant tumors in China in 2015. *Chinese Journal of Oncology*. 2019;41(1). doi: 10.3760/cma.j.issn.0253-3766.2019.01.005.

[5] Kirby M. et al. Characterising the castration-resistant prostate cancer population: a systematic review. *Int J Clin Pract*. 2011;65(11):1180-1192. doi:10.1111/j.1742-1241.2011.02799.

[6] Hong J, Kim IY et al. Nonmetastatic Castration-Resistant Prostate Cancer. *Korean J Urol*. 2014;55(3):153. doi:10.4111/kju.2014.55.3.153.

[7] 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.