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News Release

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Nubeqa™ (darolutamide) receives third approval in China for men with advanced prostate cancer

- Darolutamide is now the first and only androgen receptor inhibitor (ARi) approved in China for the treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with androgen deprivation therapy (ADT), with or without chemotherapy
- Third approval is based on positive results from the pivotal Phase III ARANOTE trial and reinforces darolutamide's established efficacy and safety for prostate cancer patients across all approved indications
- This broadened indication enables physicians to use darolutamide plus ADT, with or without chemotherapy, enabling them to better tailor treatment plans to meet the needs of men with mHSPC

Berlin, February 3, 2026 –The Chinese National Medical Products Administration (NMPA) has approved the oral androgen receptor inhibitor (ARi) Nubeqa™ (darolutamide) in combination with androgen deprivation therapy (ADT) for use in patients with metastatic hormone-sensitive prostate cancer (mHSPC). The approval is based on positive results from the pivotal Phase III ARANOTE trial, which showed that darolutamide plus ADT significantly reduced the risk of radiological progression or death by 46% compared to placebo plus ADT (HR 0.54; 95% CI 0.41–0.71; P<0.0001) in patients with mHSPC. Darolutamide plus ADT was generally well tolerated and showed lower discontinuation rates due to adverse events compared to placebo plus ADT.

Prostate cancer is the second most common cancer in men and the fifth most common cause of cancer death in men worldwide. In 2022, an estimated 1.5 million men were diagnosed with prostate cancer, and about 397,000 died from the disease worldwide.[1] In China, the burden of prostate cancer has increased significantly in recent years; it's

expected incidence and mortality rates will continue to rise in the next decade, with an estimated 315,310 new cases and 81,540 deaths by 2030.[2]

“mHSPC is a crucial treatment window to delay progression to poor prognosis mCRPC.” said Professor Xing Nianzeng, Cancer Hospital Chinese Academy of Medical Sciences, China. “Over the past decade, the treatment for mHSPC has evolved from ADT alone to combination regimens. Darolutamide, new-generation androgenreceptor inhibitor, is increasingly becoming standard therapy for mHSPC. Darolutamide plus ADT (with docetaxel in ARASENS) improves overall survival, and ARANOTE shows an effective darolutamide-based option without docetaxel for patients who cannot or will not receive chemotherapy.”

“The rising incidence of prostate cancer in China poses a serious threat to men’s health, and highlights that patients need personalized support,” said Christine Roth, Executive Vice President, Global Product Strategy and Commercialization and Member of the Pharmaceuticals Leadership Team at Bayer. “This third approval for darolutamide is supported by compelling clinical data from the ARANOTE trial which reaffirms its efficacy, safety and tolerability. Darolutamide can now be used with or without chemotherapy in China, offering physicians greater flexibility to tailor treatment plans to better meet the individual needs of patients, helping to improve clinical outcomes for men with mHSPC.”

With this latest approval, darolutamide plus ADT is indicated in China for the treatment of adult patients with mHSPC, either with or without docetaxel. Darolutamide, under the brand name Nubeqa™ is already approved in mHSPC in combination with ADT and docetaxel in over 85 markets around the world, including China. It’s also approved in combination with ADT for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease in more than 85 countries around the world, including China.

Darolutamide 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 designed to assess the efficacy and safety of darolutamide plus ADT in patients with

mHSPC. 669 patients were randomized 2:1 to receive 600 mg of darolutamide twice daily or matching placebo in addition to ADT.

The primary endpoint of this study is radiological progression-free survival (rPFS), measured as time from randomization to date of first documented radiological progressive disease or death due to any cause, whichever occurs first. Secondary endpoints include overall survival (time to death from any cause), time to first castration resistant event, time to initiation of subsequent anti- cancer therapy, time to prostate-specific antigen (PSA) progression, PSA undetectable rates, time to pain progression, and safety assessments.

Results from the Phase III ARANOTE trial presented at ESMO 2024 and published in The Journal of Clinical Oncology showed that darolutamide plus ADT significantly reduced the risk of radiological progression or death by 46% compared to placebo plus ADT (HR 0.54; 95% CI 0.41–0.71; P<0.0001), in patients with mHSPC. Consistent benefits in radiological progression-free survival (rPFS) were observed across prespecified subgroups, including patients with high-volume (HR 0.60, 95% CI: 0.44-0.80) and low-volume (HR 0.30, 95% CI: 0.15-0.60) mHSPC. The incidence of all adverse events (AE), including the incidence of serious and grade 3 and grade 4 AE, in the treatment group with darolutamide plus ADT in the ARANOTE study was comparable to placebo plus ADT. Darolutamide plus ADT was generally well tolerated and showed lower discontinuation rates due to adverse events compared to placebo plus ADT.

About darolutamide (Nubeqa™)

Darolutamide is an oral ARi with a unique chemical structure that binds with high affinity to the androgen receptor and exhibits a strong antagonistic effect against the androgen receptor inhibiting the receptor function and growth of prostate cancer cells. Additionally, preclinical models and neuroimaging data in healthy humans, support darolutamide's low potential for blood-brain barrier penetration.

Darolutamide (plus ADT or plus ADT and docetaxel) demonstrated a side effect profile, in both mHSPC registrational studies where the incidences of adverse events were similar to the respective comparator arm. With this tolerability profile and a limited risk of potentially critical interactions with other medications, darolutamide offers a very good option in treatment management for physicians and patients.

A robust clinical development program is underway investigating darolutamide across various stages of prostate cancer. Current ongoing trials include the Phase III ARASTEP trial evaluating the efficacy of darolutamide plus ADT compared to ADT alone in hormone-sensitive prostate cancer (HSPC), in patients with high-risk biochemical recurrence (BCR) who have no evidence of metastatic disease by conventional imaging and a positive PSMA PET/CT at baseline. Darolutamide is also being investigated in the collaborative Phase III DASL-HiCaP (ANZUP1801) trial led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). The study evaluates darolutamide as a treatment for localized prostate cancer in combination with radiotherapy.

About Metastatic Hormone-Sensitive Prostate Cancer

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. mHSPC is an advanced form of prostate cancer, when the cancer has spread beyond the prostate to other organs but is still responding to hormone therapy that lowers testosterone, such as androgen deprivation therapy (ADT). Despite treatment, most men with mHSPC will eventually progress to castration-resistant prostate cancer, a condition with limited survival. [3,4]

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 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. Bayer is focused on addressing the unique needs of patients with prostate cancer, developing and providing treatments that extend their lives throughout the different stages of the disease and allowing them to continue with their everyday activities, so that patients 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. In line with its mission, "Health for all, Hunger for none," the company's products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a

positive impact with its businesses. At the same time, the Group aims to increase its earning power and create value through innovation and growth. The Bayer brand stands for trust, reliability and quality throughout the world. In fiscal 2024, the Group employed around 93,000 people and had sales of 46.6 billion euros. R&D expenses amounted to 6.2 billion euros. For more information, go to www.bayer.com.

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lh (2026-0017e)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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[2] Huang Q, Zi H, Luo L *et al.* Secular trends of morbidity and mortality of prostate, bladder, and kidney cancers in China, 1990 to 2019 and their predictions to 2030. BMC Cancer. 2022 Nov 11;22(1):1164. doi: 10.1186/s12885-022-10244-9
[3] Siegel, DA et al. MMWR Morb Mortal Wkly Rep 2020; 69:1473–1480
[4] Hahn, A et al. Am Soc Clin Oncol Educ Book. 2018; 23;38:363–371