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Bayer announces expanded indication approval of Nubeqa® in India

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Nubeqa (darolutamide) is developed jointly by Bayer and Orion Corporation

Bayer has announced that its cancer drug, Nubeqa® has lately received approval in India for an expanded indication, offering clinicians access to a non-chemotherapy treatment option for patients who may not be able to tolerate chemotherapy.

The expanded approval in India allows for Nubeqa to be used in combination with androgen-deprivation therapy (ADT) for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC). Nubeqa was launched in India in June 2022 with its first approved indication for non-metastatic castration-resistant prostate cancer (nmCRPC), followed in 2023 by approval for its use together with docetaxel and ADT in metastatic disease.

In India, prostate cancer is most common in men over 50 years. As the ageing population grows, cases are expected to rise, increasing the need for treatment options that are effective, better tolerated and help improve quality of life in patients.

The expanded approval is supported by data from the global Phase III clinical study called ARANOTE that evaluated darolutamide plus ADT in men with metastatic hormone-sensitive prostate cancer. India played an important role in this trial, with 93 patients enrolled, representing about 14% of the global study population. AIIMS Delhi served as a key trial site, along with additional centres across the country.

Nubeqa (darolutamide) developed jointly by Bayer and Orion Corporation, is a next-generation androgen receptor inhibitor designed with a unique structure that results in minimal blood–brain barrier penetration, reducing the likelihood of fatigue or cognitive concerns seen with some earlier androgen receptor (AR) inhibitors. It also has low potential for drug–drug interactions, making it suitable for older patients or those managing multiple therapies.

Nubeqa is approved globally in approximately 89 countries for the treatment of mHSPC and nmCRPC, reflecting its growing role in helping clinicians manage advanced prostate cancer with evidence based, well tolerated treatment options. The latest indication for mHSPC is approved in Korea, Thailand, Taiwan, Australia, US, the EU and now India.