


DISEASE BURDEN

Prostate cancer is the second most common cancer in men and the fourth most common cancer overall (7.3% of all new cancer cases in 2020). Prostate cancer incidence rates are rising in many populations in Sub-Saharan Africa where men are approximately twice as likely to be diagnosed with prostate cancer before the age of 45 as Caucasian men.



CLINICAL RELEVANCE

Among men with nonmetastatic castration-resistant prostate cancer already receiving androgen-deprivation therapy (the standard of care for this condition), the percentage of patients who were alive at 3 years was significantly higher among those who received darolutamide than among those who received placebo.




INTELLECTUAL PROPERTY LANDSCAPE

Darolutamide primary patent has been granted in many LMICs and is expected to expire in May 2030. The patent term has been extended in few LMICs until 2035. Secondary patents have not been identified in LMICs.




SERVICE DELIVERY ENABLERS

Prostate cancer diagnosis in LMICs is hindered by limited access to diagnostic tools and healthcare resources. PSA testing, imaging, and biopsies are scarce, leading to late-stage diagnosis. Access to cost-effective second-line androgen-targeted therapies like abiraterone and enzalutamide is also inadequate in many LMICs.



REGULATORY

Product approved by stringent regulatory authorities. Potential sublicensees of darolutamide could rely on mechanism like USFDA Para III, Swissmedic MAGHP, EU-M4all for quality assurance. Bioequivalence studies are necessary. Biowaivers will not be an option.



MANUFACTURING

Standard manufacturing process for tablets. No challenges with respect to excipients or final packaging. Probable occupational exposure band category 3 manufacturing precautions might be required. Shelf life is 3 years at room temperature.



MARKET

Darolutamide's growth is evidenced by its availability in more than 80 countries including some LMICs. However, it is scarcely available in public domain and there seems to be no information on its access strategies in LMICs.

