NUBEQA—the novel AR inhibitor that extends both MFS and OS without compromising quality of life[1-3]

AR=androgen receptor; MFS=metastasis-free survival; nmCRPC=non-metastatic castration resistant prostate cancer; OS=overall survival.

References: 1. NUBEQA (Darolutamide) Approved Package Insert, Singapore, June 2020. Bayer (South East Asia) Pte Ltd. **2.** Fizazi K, Shore N, Tammela TL, et al. Darolutamide in nonmetastatic, castration-resistant prostate cancer. *N Engl J Med.* 2019;380(13):1235-1246. **3.** Fizazi K, Shore N, Tammela TL, et al. Nonmetastatic, castration-resistant prostate cancer and survival with darolutamide. *N Engl J Med.* 2020;383(11):1040-1049.

INDICATION

NUBEQA is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease.

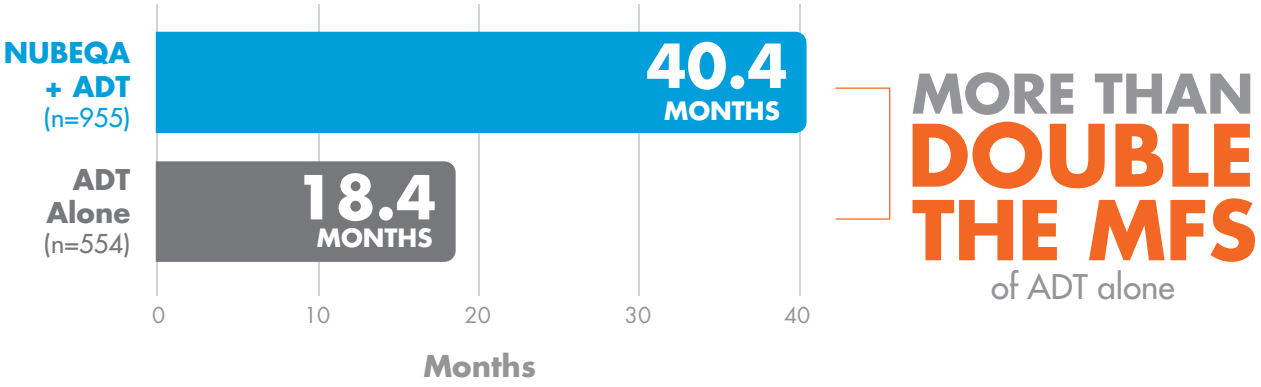
For Healthcare Professionals Only
Full prescribing information is available on request

NUBEQA®
(darolutamide) 300 mg tablets

PROVEN TO EXTEND BOTH MFS AND OS in men with nmCRPC[1-3]

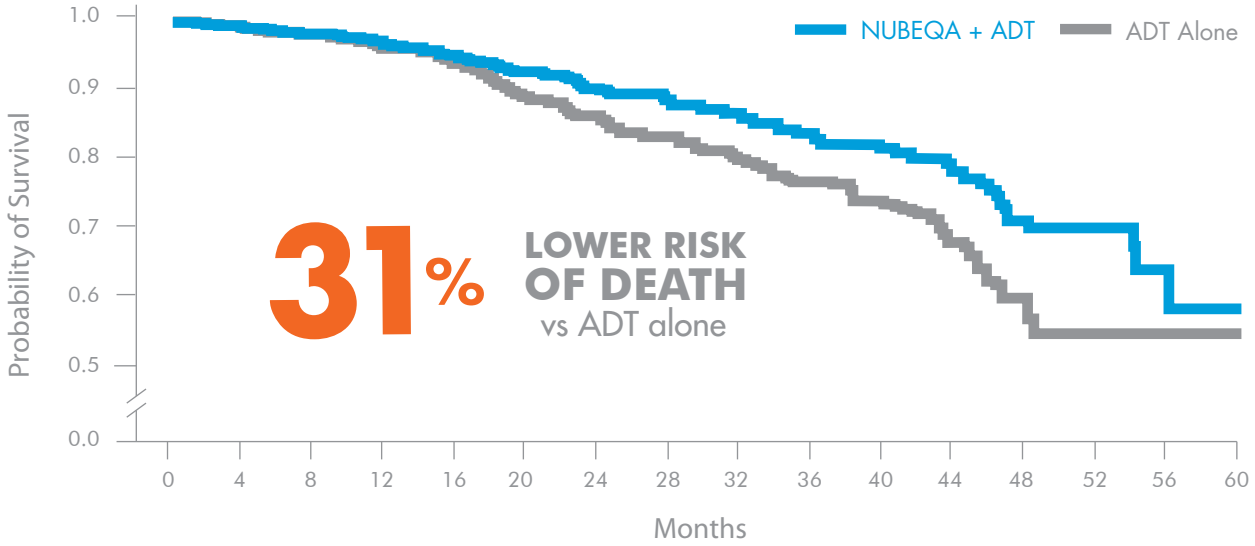
Statistically significant increase in median MFS vs ADT alone[1,2]

(HR: 0.41; 95% CI: 0.34-0.50; *P*<0.001)



Statistically significant results in extending survival[3]

(HR: 0.69; 95% CI: 0.53-0.88; *P*=0.003)

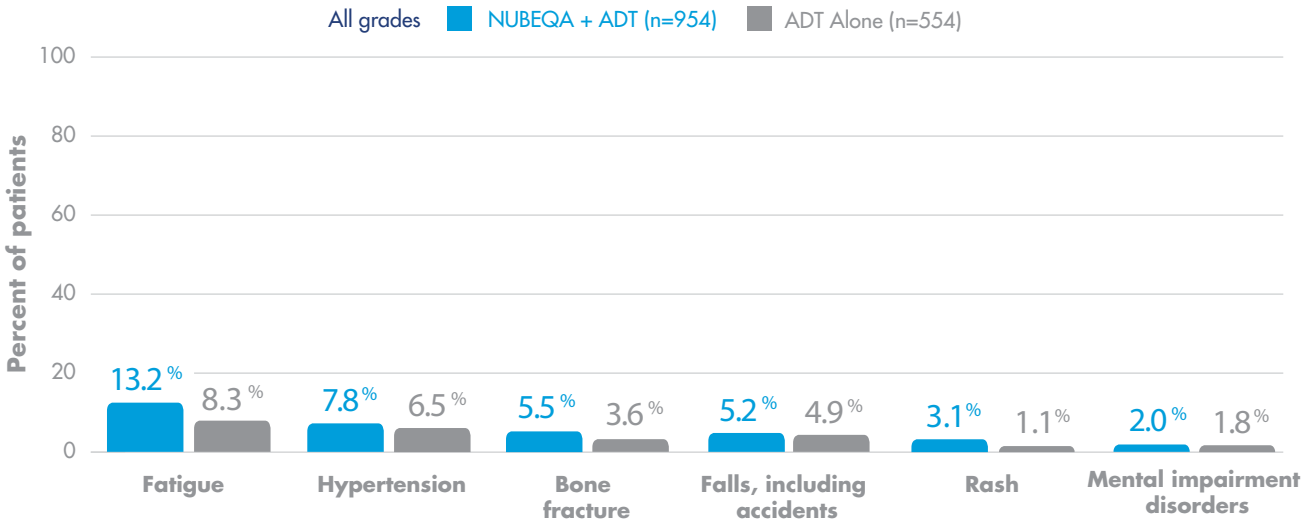


By adding NUBEQA to ADT, nmCRPC patients benefited from a statistically significant increase in both MFS and OS[1-3]

ADT=androgen deprivation therapy; CI=confidence interval; HR=hazard ratio; MFS=metastasis-free survival; nmCRPC=non-metastatic castration resistant prostate cancer; OS=overall survival.

MINIMAL DIFFERENCE IN AEs that are important to patients[1,3]

Frequency of AEs was similar with NUBEQA + ADT vs ADT alone[3]



- The proven tolerability of NUBEQA was supported by the longer-term safety analysis[1]*

Fatigue was the only AE to occur at an incidence of ≥10% with NUBEQA[1]

Even with longer follow-up*, the discontinuation rate due to AEs remained the same as in the primary analysis[2,3]

NUBEQA + ADT **8.9%** vs **ADT Alone** **8.7%**

*The longer-term safety analysis refers to the final analysis, conducted at 60 months.

ADT=androgen deprivation therapy; AEs=adverse events.

NUBEQA® (darolutamide) 300 mg tablets

FOCUS ON SURVIVAL AND TOLERABILITY
in men with nmCRPC[1-3]

NUBEQA offers proven benefits to men with non-metastatic CRPC

40 MONTHS OF MFS

Men treated with NUBEQA + ADT achieved a **median of 40 months of MFS**[1,2]

31% REDUCTION IN RISK OF DEATH

NUBEQA + ADT **reduced the risk of death** compared to ADT alone[3]

PROVEN TOLERABILITY

NUBEQA continued to show only 2% difference over ADT alone for most AEs of interest[3]*

NUBEQA extends MFS and OS with a low incidence of additional AEs

*The longer-term follow-up refers to the final analysis, conducted at 60 months.

ADT=androgen deprivation therapy; AEs=adverse events; CRPC=castration resistant prostate cancer; MFS=metastasis-free survival; nmCRPC=non-metastatic castration resistant prostate cancer; OS=overall survival.

ABBREVIATED PRESCRIBING INFORMATION

Nubeqa® (darolutamide) 300 mg film-coated tablets. Composition each film-coated tablet contains 300 mg of darolutamide. **Indication** Nubeqa is indicated for the treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease. **Posology and method of administration** Recommended dose is 600 mg darolutamide (two tablets of 300 mg) taken twice daily, equivalent to a total daily dose of 1200 mg. If a patient experiences a ≥ grade 3 toxicity or an intolerable adverse reaction, dosing should be withheld or reduced to 300 mg twice daily until symptoms improve. Treatment may then be resumed at a dose of 600 mg twice daily. Nubeqa is for oral use and tablets should be taken whole with food. **Contraindications** Hypersensitivity to the active substance or to any of the excipients. Women who are or may become pregnant. **Special warnings and precautions for use** *Renal impairment:* the available data in patients with severe renal impairment are limited. As exposure might be increased those patients should be closely monitored for adverse reactions. *Hepatic impairment:* the available data in patients with moderate hepatic impairment are limited, and darolutamide has not been studied in patients with severe hepatic impairment. As exposure might be increased those patients should be closely monitored for adverse reactions. *Recent cardiovascular disease:* patients with clinically significant disease in the past 6 months, including stroke, myocardial infarction, severe/unstable angina pectoris, coronary/peripheral artery bypass graft, and symptomatic congestive heart failure were excluded from the clinical studies. Therefore the safety of darolutamide in these patients has not been established. *Concomitant use with other medicinal products:* use of strong CYP3A4 and P-gp inducers during treatment with darolutamide may decrease the plasma concentration of darolutamide and is not recommended, unless there is no therapeutic alternative. Selection of an alternate concomitant medicinal product with less potential to induce CYP3A4 or P-gp should be considered. Patients should be monitored for adverse reactions of BCRP, OATP1B1 and OATP1B3 substrates as co-administration with darolutamide may increase the plasma concentration of these substrates. Co-administration with rosuvastatin should be avoided unless there is no therapeutic alternative. *Androgen deprivation therapy may prolong the QT interval:* in patients with a history of risk factors for QT prolongation and in patients receiving concomitant medical products that might prolong the QT interval, physician should assess the benefit-risk ratio including the potential for Torsade de pointes prior to initiating Nubeqa. *Information about excipients:* Nubeqa contains lactose. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **Undesirable effects** *Very common* fatigue/asthenic conditions, neutrophil count decreased, bilirubin increased and AST increased; *Common:* ischaemic heart disease, heart failure, rash, pain in extremity, musculoskeletal pain and fractures. For a full listing of undesirable effects, please refer to the full product insert. **For full prescribing information, please contact:** Bayer (South East Asia) Pte. Ltd. 2, Tanjong Katong Road #07-01, Paya Lebar Quarter 3, Singapore 437161. **Date of revision text:** June 2020.

References: 1. NUBEQA (Darolutamide) Approved Package Insert, Singapore, June 2020. Bayer (South East Asia) Pte Ltd. **2.** Fizazi K, Shore N, Tammela TL, et al. Darolutamide in nonmetastatic, castration-resistant prostate cancer. *N Engl J Med.* 2019;380(13):1235-1246. **3.** Fizazi K, Shore N, Tammela TL, et al. Nonmetastatic, castration-resistant prostate cancer and survival with darolutamide. *N Engl J Med.* 2020;383(11):1040-1049.

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NUBEQA® (darolutamide) 300 mg tablets