**NUBEQA is a new second-generation anti-androgen**[1,2*]

# Discover NUBEQA®

NUBEQA (darolutamide) is indicated for the treatment of patients with non-metastatic castration resistant prostate cancer (nmCRPC).

NUBEQA has not been studied in patients with nmCRPC at low risk of developing metastasis. The benefit and risk profile in these patients is unknown.

## NUBEQA + ADT significantly improved MFS vs. placebo + ADT[1†]

NUBEQA + ADT: **40.4 months**, median (34.3, NR)  Placebo + ADT: **18.4 months**, median (15.5, 22.3)

HR (95% CI): 0.41 (0.34, 0.50); $p<0.000001$

## The most frequently observed ADR (≥10%) in patients receiving NUBEQA was fatigue[‡]

15.8% of patients experienced fatigue (including asthenia, malaise and lethargy) with NUBEQA + ADT vs. 11.4% with placebo + ADT

**Clinical use**

- Pediatrics (<18 years of age): Not authorized for pediatric use

**Relevant warnings and precautions**

- Not indicated in women
- May cause harm to developing fetus or lead to loss of pregnancy if engaging in sexual activity with women; a condom and/or other highly effective contraceptive should be used during treatment and for 3 months after completion of treatment with NUBEQA
- May impair fertility, patients should be advised not to donate sperm during treatment and for 3 months after
- Monitor for disease progression radiographically in addition to PSA

**For more information**

Consult the Product Monograph at https://www.bayer.ca/omr/online/nubeqa-pm-en.pdf for important information relating to adverse reactions, interactions and dosing information. The Product Monograph is also available by calling Bayer Medical Information at 1-800-265-7382.

ADR=adverse drug reaction.
* Clinical significance unknown.
† ARAMIS, a phase III, randomized, double-blind, placebo-controlled, multicentre clinical study to assess NUBEQA (n=955) vs. placebo (n=554) in patients with nmCRPC. Patients were randomized 2:1 to receive NUBEQA 600 mg orally twice daily, or matching placebo. All patients received a gonadotropin-releasing hormone (GnRH) analog concurrently or had a bilateral orchiectomy. Treatment with NUBEQA continued until radiographic disease progression as assessed by conventional imaging (CT, MRI, Tc99m bone scan) by blinded central review, unacceptable toxicity or withdrawal. The primary efficacy endpoint was metastasis free survival (MFS) which was defined as the time from randomization to confirmed evidence of metastasis or death from any cause, whichever occurred first.
‡ Includes asthenia, fatigue, malaise, lethargy.

**References: 1.** NUBEQA® Product Monograph, Bayer Inc., February 19, 2020. **2.** Mottet N, et al. 2020 European Association of Urology 2020 Guidelines on Prostate Cancer. Available at: uroweb.org/guideline/prostate-cancer. Accessed April 7, 2020.



℞ NUBEQA® (darolutamide) 300 mg tablets

PP-NUB-CA-0035-1