{{customText[Hello |Hi |Dear]}} {{customText[Dr. |Mr. |Mrs. |Ms. |Professor|]}}
{{customText[##accFname##|##accLname##|##accFname##
##accLname##]}},

{{customRichText}}

I would like to share the following information that may be of interest to you and relevant to your clinical practice.

XTANDI® (enzalutamide capsules) is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).[1]

WHEN mCSPC STRIKES, CHOOSE XTANDI.

XTANDI + ADT demonstrated overall survival benefits in both the ARCHES and ENZAMET Phase 3 trials

ARCHES* OS (PRESPECIFIED FINAL ANALYSIS)[1]

XTANDI + ADT† demonstrated SUPERIOR OS vs. placebo + ADT†

34% REDUCTION IN RISK OF DEATH
HR 0.66; 95% CI, 0.53, 0.81; *p*<0.0001 (secondary endpoint)

% of events: 26.8% vs. 35.1%

Median OS: Not reached in both arms

At 4 years, the percentage of patients assigned to XTANDI + ADT† (vs. placebo + ADT) estimated to be alive were 71% vs. 57%

Similar results were demonstrated in the investigator-led ENZAMET‡ trial.

Download a summary of the ARCHES & ENZAMET trials:

SUMMARY OF THE ARCHES & ENZAMET TRIALS

View the details about study design, clinical data and safety data.

Open Summary

For more information about XTANDI, please feel free to reach me via the contact information provided at the bottom of this email.

Important Safety Information

Indications and clinical use:

XTANDI® (enzalutamide capsules) is indicated for the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk of metastasis (high-risk BCR).

XTANDI is indicated for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

XTANDI is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC). XTANDI has not been studied in patients with nmCRPC at low risk of developing metastatic disease. The benefit and risk profile in these patients is unknown.

XTANDI is indicated in the setting of medical or surgical castration for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients who:

- are chemotherapy-naïve with asymptomatic or mildly symptomatic disease after failure of androgen deprivation therapy.
- have received docetaxel therapy.

The safety and efficacy of XTANDI has not been established for patients less than 18 years of age.

Contraindication:

Women who are or may become pregnant, or who are lactating.

Most serious warnings and precautions:

Seizures: increased risk. Seizure risk may be dose dependent with a greater risk at daily doses higher than 160 mg. XTANDI should be used with caution in patients with a history of seizures or other predisposing risk factors for seizures. Permanently discontinue XTANDI in patients who develop a seizure during treatment.

Posterior Reversible Encephalopathy Syndrome (PRES): There have been reports of PRES in patients receiving XTANDI; discontinuation is recommended in patients who develop PRES.

Other relevant warnings and precautions:

- Drug contains sorbitol; avoid in patients with hereditary fructose intolerance

- XTANDI induces CYP3A4, CYP2C9 and CYP2C19; avoid concomitant use or dose adjust with drugs with a narrow therapeutic range that are substrates of these enzymes
- Concomitant use of strong CYP3A4 inducers with XTANDI is not recommended
- XTANDI is metabolized by CYP2C8. Avoid concomitant use or adjust XTANDI dose with strong CYP2C8 inhibitors
- Increased incidence of neoplastic findings, considered related to the primary pharmacology of enzalutamide, seen in rats after two years of daily administration of enzalutamide
- Monitor for signs and symptoms of ischemic heart disease; discontinue XTANDI for Grade 3-4 ischemic heart disease
- Safety not established in patients with clinically significant cardiovascular disease
- Associated with QTc prolongation; monitor ECG and electrolytes for patients at risk
- Associated with an increased risk of hypertension; monitor blood pressure periodically
- Hypersensitivity reactions (including, but not limited to, face, tongue, lip and pharyngeal oedema) have been observed with XTANDI. Patients who experience any symptoms should temporarily discontinue and promptly seek medical care.
- Permanently discontinue for serious reactions.
- Associated with non-pathological bone fractures
- Risk of falls and fall-related injuries
- Neuropsychiatric adverse events, including seizure, memory impairment and hallucination
- Associated with mental impairment disorders; risk of engaging in any activity where mental impairment or sudden loss of consciousness could cause serious harm to themselves or others
- Advise on use of contraception
- May affect male fertility (based on animal studies)
- Caution is advised in patients with severe renal impairment or end-stage renal disease
- nmCSPC, high-risk BCR or nmCRPC patients should be monitored for disease progression radiographically at physician discretion in addition to serum Prostate Specific Antigen (PSA)

For more information:

Please consult the product monograph for important information relating to adverse reactions, interactions and dosing which have not been discussed in this piece. The product monograph is also available by calling Medical Information at 1-888-338-1824.

Sincerely,

{{userName}}

Astellas Pharma Canada, Inc.
675 Cochrane Drive, Suite 650, West Tower
Markham, Ontario, Canada L3R 0B8
Email: {{User.Email}}
Mobile: {{User.Phone}}

* ARCHES trial: Phase 3, randomized, placebo-controlled, multicentre trial of 1150 patients with mCSPC as confirmed by positive bone scan or metastatic lesions on CT or MRI scan. Patients were randomized 1:1 to receive treatment orally once daily with XTANDI 160 mg (n=574) or placebo (n=576). Treatment with concurrent docetaxel was not allowed. rPFS was defined as the time from randomization to the first objective evidence of radiographic disease progression or death (any cause from time of randomization through 24 weeks after study drug discontinuation), whichever occurred first. The primary analysis cut-off date was October 14, 2018 and the prespecified final analysis cut-off date was May 28, 2021.[1]

† All patients continued on a GnRH analogue or had prior bilateral orchiectomy.[1]

‡ ENZAMET trial: Phase 3, randomized, open-label, placebo-controlled, multicentre trial of 1125 patients with mCSPC as confirmed by positive bone scan or metastatic lesions on CT scan. Patients were randomized 1:1 to receive treatment orally once daily with XTANDI 160 mg (n=563) or standard nonsteroidal antiandrogen drug (bicalutamide, nilutamide or flutamide; n=562). Treatment with concurrent docetaxel was per investigator discretion. The primary analysis was overall survival.[2]

ADT=androgen deprivation therapy; CI=confidence interval; CT=computerized tomography; GnRH=gonadotropin-releasing hormone; HR=hazard ratio; mCRPC=metastatic castration-resistant prostate cancer; mCSPC=metastatic castration-sensitive prostate cancer; MRI=magnetic resonance imaging; nmCRPC=non-metastatic castration-resistant prostate cancer; OS=overall survival; rPFS=radiographic progression-free survival.

References: 1. XTANDI Product Monograph. Astellas Pharma Canada, Inc. January 5, 2024.
2. Davis ID, Martin AJ, Stockler MR, *et al. N Engl J Med*. 2019;38(2):121-131.

Xtandi (enzalutamide) capsules

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