mCSPC DATA IN THE TITAN STUDY

HE NEVER THOUGHT HE'D SEE THE DAY. HELP HIM BE THERE™.

Some of his best moments may not have happened yet. ERLEADA® may help him be there to experience them.[1]

START EARLY WITH ERLEADA®

INDICATIONS

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with:

- Metastatic castration-sensitive prostate cancer (mCSPC)
- Non-metastatic castration-resistant prostate cancer (nmCRPC)

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Cerebrovascular and Ischemic Cardiovascular Events — In a randomized study (SPARTAN) of patients with nmCRPC, ischemic cardiovascular events occurred in 3.7% of patients treated with ERLEADA® and 2% of patients treated with placebo. In a randomized study (TITAN) in patients with mCSPC, ischemic cardiovascular events occurred in 4.4% of patients treated with ERLEADA® and 1.5% of patients treated with placebo.

Across the SPARTAN and TITAN studies, 4 patients (0.3%) treated with ERLEADA® and 2 patients (0.2%) treated with placebo died from an ischemic cardiovascular event. Patients with history of unstable angina, myocardial infarction, congestive heart failure, stroke, or transient ischemic attack within 6 months of randomization were excluded from the SPARTAN and TITAN studies.

Please see Important Safety Information throughout and on pages 10-11.

Please see enclosed full Prescribing Information for ERLEADA®.

Erleada® (apalutamide) 60 mg tablets

HE MAY LIVE LONGER. HELP HIM BE THERE FOR THE THINGS THAT MATTER TO HIM.

TITAN dual primary endpoint, final analysis

ERLEADA® + ADT DEMONSTRATED SUPERIOR OS IN MEN WITH mCSPC VS ADT ALONE[1-3]

35%

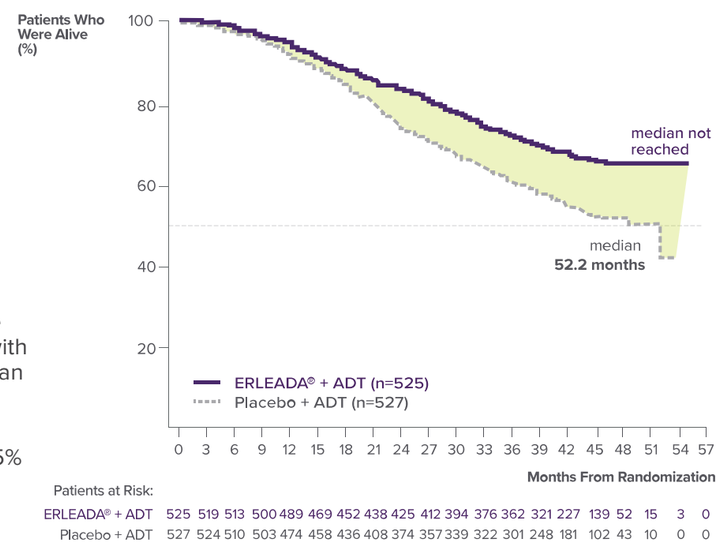
Reduction in the risk of death

HR=0.65; 95% CI: 0.53, 0.79

Median OS was not reached in the ERLEADA® + ADT arm compared with 52.2 months in the ADT arm. Median follow-up time was 44.0 months.[2]

TITAN primary analysis results: Median OS: NE vs NE; HR=0.67; 95% CI: 0.51, 0.89; *P*=0.0053. Median follow-up time was 22.7 months.[1,2]

OVERALL SURVIVAL



Patients at Risk:

ERLEADA® + ADT	525	519	513	500	489	469	452	438	425	412	394	376	362	321	227	139	52	15	3	0
Placebo + ADT	527	524	510	503	474	458	436	408	374	357	339	322	301	248	181	102	43	10	0	0

TITAN STUDY DESIGN: TITAN was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial. Patients had newly diagnosed mCSPC or relapsed metastatic disease after an initial diagnosis of localized disease (N=1052). Patients with visceral (ie, liver or lung) metastases as the only sites of metastases were excluded. Patients were randomized 1:1 to receive ERLEADA® 240 mg orally once daily + ADT or placebo orally once-daily + ADT. All patients received a concomitant GnRH analog or had a prior bilateral orchiectomy. The dual primary endpoints were OS and rPFS. rPFS was estimated as the time from random assignment to first imaging-based documentation of disease progression or death, whichever occurred first; rPFS was prespecified to be final coinciding with the first interim analysis of OS and is not updated in this analysis. OS was defined as the time from random assignment to date of death from any cause.[1,2,4]

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (continued)

In the SPARTAN study, cerebrovascular events occurred in 2.5% of patients treated with ERLEADA® and 1% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA® and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, 3 patients (0.2%) treated with ERLEADA®, and 2 patients (0.2%) treated with placebo died from a cerebrovascular event.

TITAN dual primary endpoint, final analysis

NEARLY 2 OUT OF 3 PATIENTS IN THE ERLEADA® + ADT ARM WERE ALIVE AT 4 YEARS[2,5]

The overall survival rate at 48 months was

65.1%

for ERLEADA® + ADT patients vs 51.8% for patients taking placebo + ADT[2]

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (continued)

Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

Falls — In a randomized study (SPARTAN), falls occurred in 16% of patients treated with ERLEADA® compared with 9% of patients treated with placebo. Falls were not associated with loss of consciousness or seizure. Falls occurred in patients receiving ERLEADA® with increased frequency in the elderly. Evaluate patients for fall risk.

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HE MAY LIVE LONGER. HELP HIM BE THERE FOR THE THINGS THAT MATTER TO HIM.

TITAN dual primary endpoint, primary analysis

ERLEADA® + ADT DEMONSTRATED SUPERIOR rPFS VS ADT ALONE[1,3,6]

52%

Reduction in the risk of radiographic progression or death

HR=0.48; 95% CI: 0.39, 0.60; *P*<0.0001

Median follow-up time was 22.7 months.[6]
ERLEADA® + ADT improved rPFS vs placebo + ADT in a range of patient types with mCSPC. rPFS improved regardless of high- or low-volume disease, prior docetaxel use, or Gleason score at diagnosis.[6]

IMPORTANT SAFETY INFORMATION (CONTINUED)

WARNINGS AND PRECAUTIONS (continued)

Seizure — In two randomized studies (SPARTAN and TITAN), 5 patients (0.4%) treated with ERLEADA® and 1 patient treated with placebo (0.1%) experienced a seizure. Permanently discontinue ERLEADA® in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with ERLEADA®. Advise patients of the risk of developing a seizure while receiving ERLEADA® and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

Severe Cutaneous Adverse Reactions — Fatal and life-threatening cases of severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome/toxic epidermal necrolysis (SJS/TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) occurred in patients receiving ERLEADA®.

Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other Grade 4 skin reactions, permanently discontinue ERLEADA® *[see Dosage and Administration (2.2)]*.

Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on findings from animals and its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® *[see Use in Specific Populations (8.1, 8.3)]*.

AN ESTABLISHED SAFETY PROFILE

Serious adverse reactions occurred in 20% of patients in the ERLEADA® + ADT arm and 20% in the placebo + ADT arm. The discontinuation rate due to adverse reactions was 8% in the ERLEADA® + ADT arm.[1]

Adverse Reactions (All Grades) With ≥10% Incidence in the ERLEADA® + ADT Arm That Occurred With at Least 2% Greater Frequency Than in the Placebo + ADT Arm in the TITAN STUDY[1]

Adverse Reactions	ERLEADA® + ADT (n=524)	Placebo + ADT (n=527)
Rash	28%	9%
Hot flush	23%	16%
Hypertension	18%	16%
Arthralgia	17%	15%
Pruritus	11%	4.6%

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

Laboratory Abnormalities — All Grades (Grade 3-4)

- **Hematology —** In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA® 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA® 41% (1.8%), placebo 21% (1.6%)
- **Chemistry —** In the TITAN study: hypertriglyceridemia ERLEADA® 17% (2.5%), placebo 12% (2.3%). In the SPARTAN study: hypercholesterolemia ERLEADA® 76% (0.1%), placebo 46% (0%); hyperglycemia ERLEADA® 70% (2%), placebo 59% (1.0%); hypertriglyceridemia ERLEADA® 67% (1.6%), placebo 49% (0.8%); hyperkalemia ERLEADA® 32% (1.9%), placebo 22% (0.5%)

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TITAN pre-specified exploratory endpoint

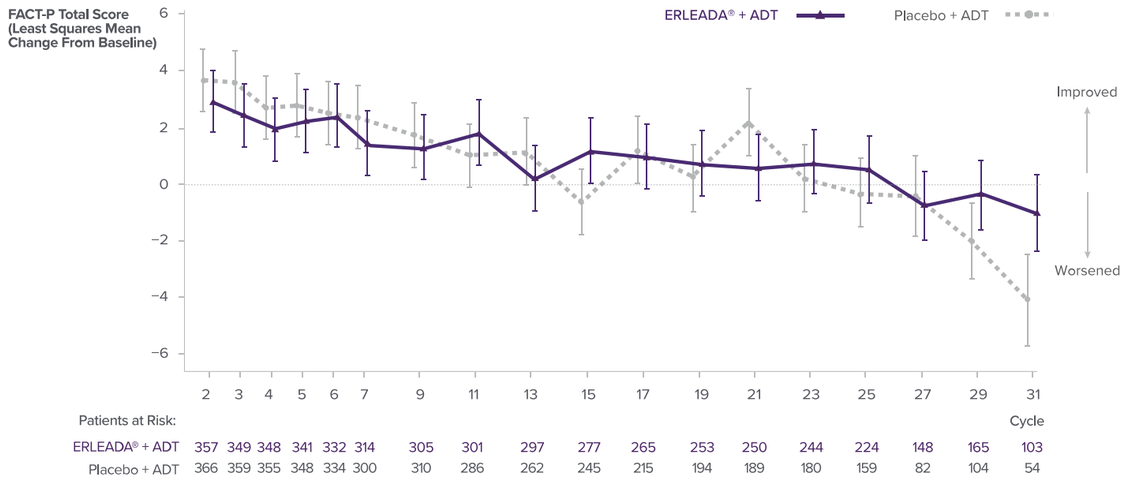
PATIENTS MAINTAINED HRQoL WHILE TAKING ERLEADA® + ADT[2]

HRQoL based on patient-reported outcomes is not reported in the ERLEADA® Prescribing Information. HRQoL should be viewed in the context of patient management and the overall physical condition and clinical course of the patient.

Median follow-up was 44.0 months.

Analysis of change from baseline in the FACT-P total score showed no substantial between-group differences.*

Mean Change From Baseline in FACT-P Total Score[2]



Patients at Risk:																		
ERLEADA® + ADT	357	349	348	341	332	314	305	301	297	277	265	253	250	244	224	148	165	103
Placebo + ADT	366	359	355	348	334	300	310	286	262	245	215	194	189	180	159	82	104	54

*The FACT-P patient-reported outcome questionnaire was used to assess prostate cancer symptoms, pain-related symptoms, and overall HRQoL. The FACT-P is a 39-item questionnaire developed and validated specially in patients with prostate cancer. The scores for 5 FACT-P subscales (physical well-being, social and family well-being, emotional well-being, functional well-being, and prostate cancer subscale) can be added together to make a single overall score that ranges from 0-156. Higher values of FACT-P total and all subscales indicate a higher HRQoL. In the TITAN study, the FACT-P was completed during Cycles 1 to 7, then every other cycle until the end of treatment, and at months 4, 8, and 12 in follow-up. Each treatment was 28 days.[7,8]

IMPORTANT SAFETY INFORMATION (CONTINUED)

ADVERSE REACTIONS (continued)

Rash — In 2 randomized studies (SPARTAN and TITAN), rash was most commonly described as macular or maculopapular. Adverse reactions of rash were 26% with ERLEADA® vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) vs placebo (0.5%).

The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines, topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 28% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

Hypothyroidism — In 2 randomized studies (SPARTAN and TITAN), hypothyroidism was reported for 8% of patients treated with ERLEADA® and 1.5% of patients treated with placebo based on assessments of thyroid-stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA® and 7% of patients treated with placebo. The median onset was at the first scheduled assessment. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose adjusted.

DRUG INTERACTIONS

Effect of Other Drugs on ERLEADA® — Co-administration of a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA® dose based on tolerability *[see Dosage and Administration (2.2)]*.

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Please see enclosed full Prescribing Information for ERLEADA®.

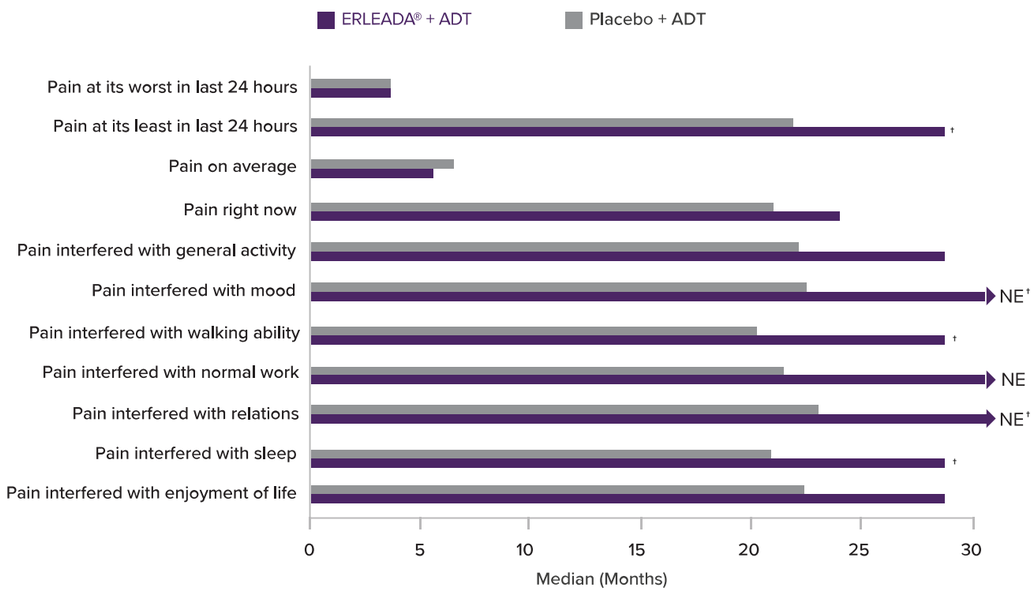
Erleada® (apalutamide) 60 mg tablets

PATIENTS MAINTAINED HRQoL WHILE TAKING ERLEADA® + ADT

TITAN post hoc analysis

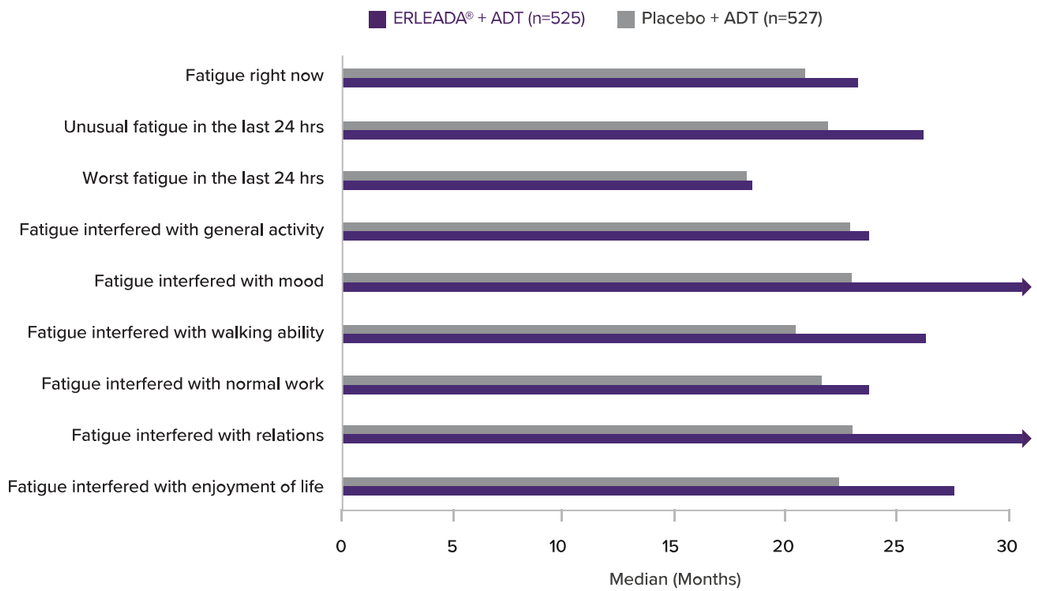
POST HOC ANALYSIS OF PAIN AND FATIGUE IN THE TITAN STUDY[9]

Time to Deterioration in Pain*[9]



*Based on individual questions from Brief Pain Inventory-Short Form administered to patients (TITAN study).[9]
†*P*<0.05 for ERLEADA® vs placebo.[9]

Time to Deterioration in Fatigue‡[9]



‡Based on individual questions from Brief Fatigue Inventory administered to patients (TITAN study).[9]

IMPORTANT SAFETY INFORMATION (CONTINUED)

DRUG INTERACTIONS (continued)

Effect of ERLEADA® on Other Drugs

CYP3A4, CYP2C9, CYP2C19, and UGT Substrates — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

IMPORTANT SAFETY INFORMATION (CONTINUED)

DRUG INTERACTIONS (continued)

P-gp, BCRP, or OATP1B1 Substrates — Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

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INDICATIONS

ERLEADA® (apalutamide) is an androgen receptor inhibitor indicated for the treatment of patients with:

- Metastatic castration-sensitive prostate cancer (mCSPC)
- Non-metastatic castration-resistant prostate cancer (nmCRPC)

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In the SPARTAN study, cerebrovascular events occurred in 2.5% of patients treated with ERLEADA® and 1% of patients treated with placebo. In the TITAN study, cerebrovascular events occurred in 1.9% of patients treated with ERLEADA® and 2.1% of patients treated with placebo. Across the SPARTAN and TITAN studies, 3 patients (0.2%) treated with ERLEADA®, and 2 patients (0.2%) treated with placebo died from a cerebrovascular event.

Cerebrovascular and ischemic cardiovascular events, including events leading to death, occurred in patients receiving ERLEADA®. Monitor for signs and symptoms of ischemic heart disease and cerebrovascular disorders. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of ERLEADA® for Grade 3 and 4 events.

Fractures — In a randomized study (SPARTAN) of patients with nmCRPC, fractures occurred in 12% of patients treated with ERLEADA® and in 7% of patients treated with placebo. In a randomized study (TITAN) of patients with mCSPC, fractures occurred in 9% of patients treated with ERLEADA® and in 6% of patients treated with placebo. Evaluate patients for fracture risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents.

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Monitor patients for the development of SCARs. Advise patients of the signs and symptoms of SCARs (eg, a prodrome of fever, flu-like symptoms, mucosal lesions, progressive skin rash, or lymphadenopathy). If a SCAR is suspected, interrupt ERLEADA® until the etiology of the reaction has been determined. Consultation with a dermatologist is recommended. If a SCAR is confirmed, or for other Grade 4 skin reactions, permanently discontinue ERLEADA® *[see Dosage and Administration (2.2)]*.

Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on findings from animals and its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® *[see Use in Specific Populations (8.1, 8.3)]*.

ADVERSE REACTIONS

The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

Laboratory Abnormalities — All Grades (Grade 3-4)

- **Hematology —** In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: anemia ERLEADA® 70% (0.4%), placebo 64% (0.5%); leukopenia ERLEADA® 47% (0.3%), placebo 29% (0%); lymphopenia ERLEADA® 41% (1.8%), placebo 21% (1.6%)
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CYP3A4, CYP2C9, CYP2C19, and UGT Substrates — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

P-gp, BCRP, or OATP1B1 Substrates — Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

Please see enclosed full Prescribing Information for ERLEADA®.

cp-50507v6

ADT = androgen deprivation therapy; CI = confidence interval; FACT-P = Functional Assessment of Cancer Therapy - Prostate; GnRH = gonadotropin-releasing hormone; HRQoL = health-related quality of life; HR = hazard ratio; mCSPC = metastatic castration-sensitive prostate cancer; NE = not estimable; NR = not reached; OS = overall survival; PSA = prostate-specific antigen; rPFS = radiographic progression-free survival; TITAN = Targeted Investigational Treatment Analysis of Novel Anti androgen.

References:

1. ERLEADA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Chi KN, Chowdhury S, Bjartell A, et al. Apalutamide in patients with metastatic castration-sensitive prostate cancer: final survival analysis of the randomized, double-blind, phase III TITAN study. *J Clin Oncol.* 2021;39(20):2294-2303. **3.** A study of apalutamide (JNJ-56021927, ARN-509) plus androgen deprivation therapy (ADT) versus ADT in participants with mHSPC (TITAN). ClinicalTrials.gov identifier: NCT02489318. Updated October 26, 2022. Accessed November 17, 2022. https://www.clinicaltrials.gov/ct2/show/NCT02489318 **4.** Chi KN, Agarwal N, Bjartell A, et al. Apalutamide for metastatic, castration-sensitive prostate cancer. Protocol. *N Engl J Med.* 2019;381:13-24. Accessed November 17, 2022. https://www.nejm.org/doi/suppl/10.1056/NEJMoa1903307/suppl_file/nejmoa1903307_protocol.pdf **5.** Data on file. Janssen Biotech, Inc. **6.** Chi KN, Agarwal N, Bjartell A, et al. Apalutamide for metastatic, castration-sensitive prostate cancer. *N Engl J Med.* 2019;381(1):13-24. **7.** Agarwal N, McQuarrie K, Bjartell A, et al; TITAN Investigators. Health-related quality of life after apalutamide treatment in patients with metastatic castration-sensitive prostate cancer (TITAN): a randomised, placebo-controlled, phase 3 study. *Lancet Oncol.* 2019;20(11):1518-1530. **8.** Agarwal N, McQuarrie K, Bjartell A, et al; TITAN Investigators. Health-related quality of life after apalutamide treatment in patients with metastatic castration-sensitive prostate cancer (TITAN): a randomised, placebo-controlled, phase 3 study. Supplement. *Lancet Oncol.* 2019;20(11):1518-1530. **9.** Agarwal N, McQuarrie K, Bjartell A, et al. Apalutamide plus androgen deprivation therapy for metastatic castration-sensitive prostate cancer: analysis of pain and fatigue in the phase 3 TITAN study. *J Urol.* 2021;206(4):914-923. **10.** Managed Markets Insights and Technology (MMIT), February 2022.

Erleada® (apalutamide) 60 mg tablets

START EARLY WITH ERLEADA®

TO HELP HIM LIVE LONGER AND BE THERE FOR THE THINGS THAT MATTER.

PROVEN SURVIVAL BENEFIT

TITAN dual primary endpoint, final analysis

ERLEADA® + ADT REDUCED THE RISK OF DEATH BY 35% IN mCSPC VS ADT ALONE[1,2]

Median OS: NR vs 52.2 months; HR=0.65; 95% CI: 0.53, 0.79; Median follow-up: 44.0 months.

MAINTAINED PATIENTS' HEALTH-RELATED QUALITY OF LIFE

Patients maintained their HRQoL, including measures of pain and fatigue, with ERLEADA® + ADT after a median follow-up of 44.0 months.[2]

ESTABLISHED SAFETY PROFILE

In TITAN, serious adverse reactions occurred in 20% of patients in the ERLEADA® + ADT arm and 20% in the placebo + ADT arm.[1]

COMPREHENSIVE PATIENT COVERAGE

ERLEADA® is covered for **93%** of commercial patients and **97%** of Medicare Part D patients.[10]

LEARN ABOUT THE IMPORTANCE OF PSA EXPLORATORY DATA

Scan for more.

Erleada® (apalutamide) 60 mg tablets

Janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson