

Erleada[™] (apalutamide) – New drug approval

- On February 14, 2018, the <u>FDA announced</u> the approval of Janssen Biotech's <u>Erleada</u>
 (<u>apalutamide</u>), for the treatment of patients with non-metastatic, castration-resistant prostate cancer
 (NM-CRPC).
- According to the <u>National Cancer Institute</u>, in 2017 approximately 161,360 American men were diagnosed with prostate cancer, and 26,730 were expected to die of the disease.
 - Approximately 10 20% of prostate cancer cases are castration-resistant, and up to 16% of these patients show no evidence that the cancer has spread at the time of the diagnosis.
- Erleada works by blocking the effect of androgens on the tumor. These androgens, such as testosterone, can promote tumor growth.
- The efficacy and safety of Erleada were demonstrated in a placebo-controlled study of 1,207
 patients with NM-CRPC. The major efficacy outcome of the study was metastasis-free survival
 (MFS).
 - The median MFS for patients taking Erleada was 40.5 months vs. 16.2 months for patients taking a placebo (HR = 0.28 [95% CI: 0.23, 0.35]; p < 0.0001).
 - In addition, statistically significant improvements were seen in time to metastasis, progression free survival, and time to symptomatic progression in the Erleada-treated patients vs. the placebo-treated patients.
 - The overall survival data were not mature at the time of final MFS analysis.
- Erleada is contraindicated in pregnancy.
- Warnings and precautions of Erleada include falls, fractures, and seizures.
- The most common adverse reactions (≥ 10%) with Erleada use include fatigue, hypertension, rash, diarrhea, nausea, decreased weight, arthralgia, fall, hot flush, decreased appetite, fracture, and peripheral edema.
- The recommended dose of Erleada is 240 mg (four 60 mg tablets) administered orally once daily.
 - Patients should also receive a gonadotropin-releasing hormone analog concurrently or should have had a bilateral orchiectomy.
- Janssen's launch plans for Erleada are pending. Erleada will be available as 60 mg tablets.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2018 Optum, Inc. All rights reserved.