

## Erleada™ (apalutamide) – New drug approval

- On February 14, 2018, the [FDA announced](#) the approval of Janssen Biotech's [Erleada \(apalutamide\)](#), for the treatment of patients with non-metastatic, castration-resistant prostate cancer (NM-CRPC).
- According to the [National Cancer Institute](#), 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 ( $\geq 10\%$ ) 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.