Tlando™ (testosterone undecanoate) – New drug approval

- On March 29, 2022, Antares Pharma announced the FDA approval of Tlando (testosterone undecanoate), for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:
    - Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range.
    - Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range.
- Safety and efficacy of Tlando in males less than 18 years old have not been established.
- The efficacy of Tlando was established in an open-label, single-arm study in 95 adult hypogonadal male patients. Patients received Tlando for approximately 24 days. The primary endpoint was the percentage of patients who achieved a 24-hour average serum testosterone concentration (Cavg0-24h) within the normal range of 300 to 1080 ng/dL on the final visit of the study
    - Overall, 80% (95% CI: 72, 88) of patients met the primary endpoint.
- Tlando carries a boxed warning for blood pressure increases.
- Tlando is contraindicated in:
    - Patients with carcinoma of the breast or known or suspected carcinoma of the prostate
    - Women who are pregnant
    - Known hypersensitivity to testosterone undecanoate or any of Tlando's ingredients
    - Men with hypogonadal conditions, such as "age-related hypogonadism", that are not associated with structural or genetic etiologies.
- Additional warnings and precautions for Tlando include polycythemia; cardiovascular risk; worsening of benign prostatic hyperplasia and potential risk of prostate cancer; venous thromboembolism; abuse of testosterone and monitoring of serum testosterone concentrations; not for use in women; potential for adverse effects on spermatogenesis; hepatic adverse effects; edema; sleep apnea; gynecomastia; lipid changes; hypercalcemia; decreased thyroxine-binding globulin; and increases in prolactin.
- The most common adverse reactions (≥ 2%) with Tlando use were increased blood prolactin, hypertension, increased hematocrit, upper respiratory tract infection, weight increased, headache, and musculoskeletal pain.
- The recommended dosage of Tlando is 225 mg (taken as two 112.5 mg capsules), orally twice daily, once in the morning and once in the evening.
    - Tlando is not substitutable with other oral testosterone undecanoate products.

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- Antares Pharma plans to launch Tlando in the second quarter of 2022. Tlando will be available as a 112.5 mg capsule