Jatenzo® (testosterone undecanoate) – New drug approval

- On March 27, 2019, the FDA announced the approval of Clarus Therapeutics' Jatenzo (testosterone undecanoate) capsules for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone, including primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).
    - The safety and efficacy of Jatenzo in males < 18 years old have not been established.
    - Jatenzo is a Schedule III controlled substance
- Jatenzo is a first-in-class soft gel oral formulation of testosterone. Oral testosterone is currently available as Striant® buccal system. Striant shares the same indication as Jatenzo.
- The efficacy and safety of Jatenzo was demonstrated in an open-label study of 166 men with hypogonadism. Study participants initially were given Jatenzo at a dose of 237 mg twice per day, and the dose was adjusted downward or upward to a maximum of 396 mg twice per day on the basis of testosterone levels. The primary endpoint was the percentage of patients with a mean plasma total testosterone concentration within a normal range.
    - Eighty-seven percent of Jatenzo-treated men achieved an average testosterone level within the normal range.
- Jatenzo carries a boxed warning for increases in blood pressure.
- Jatenzo is contraindicated in men with carcinoma of the breast or known or suspected carcinoma of the prostate, women who are pregnant, men with known hypersensitivity to Jatenzo or any of its ingredients, and in men with hypogonadal conditions such as "age-related hypogonadism", that are not associated with structural or genetic etiologies.
- Additional warnings and precautions of Jatenzo include polycythemia, cardiovascular risk, worsening of benign prostatic hyperplasia and potential risk of prostate cancer, venous thromboembolism, abuse of testosterone and monitoring of testosterone concentrations, not for use in women, potential for adverse effects on spermatogenesis, hepatic adverse effects, edema, gynecomastia, sleep apnea, lipids, hypercalcemia, decreased thyroxine-binding globulin, and risk of depression and suicide.
- The most common adverse reaction (> 2%) with Jatenzo use were polycythemia, diarrhea, dyspepsia, eructation, peripheral edema, nausea, increased hematocrit, headache, prostatomegaly, and hypertension.
- The recommended starting dosage of Jatenzo is 237 mg taken orally twice daily, once in the morning and once in the evening.
    - Prior to initiating Jatenzo, the diagnosis of hypogonadism should be confirmed by ensuring that serum testosterone concentrations have been measured in the morning on at least two separate days and that these concentrations are below the normal range.
    - Jatenzo is taken with food.

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- Clarus Therapeutics plans to launch Jatenzo before the end of the year. Jatenzo will be available as 158 mg, 198 mg, and 237 mg capsules.