June 9, 2022

Clarus Therapeutics to Present New Data for JATENZO® (testosterone undecanoate) at ENDO 2022, the Endocrine Society's Annual Meeting

JATENZO is the first FDA-approved oral softgel for testosterone replacement therapy in adult males who have deficient testosterone due to certain medical conditions

NORTHBROOK, Ill., June 09, 2022 (GLOBE NEWSWIRE) -- Clarus Therapeutics Holdings, Inc. ("Clarus") (Nasdaq:CRXT), a pharmaceutical company dedicated to providing solutions to unmet medical needs by advancing androgen and metabolic therapies for men and women, today announced that new data for JATENZO (testosterone undecanoate) will be presented in the form of an abstract at ENDO 2022, the Endocrine Society's annual meeting, taking place at the Georgia World Congress Center in Atlanta June 11-14, 2022.

Details on the abstract presentation for JATENZO are below.

Abstract Title: Comparison Between Single Time Point Testing and 24-Hour Average Concentration of Total Testosterone in Hypogonadal Men Treated with an Oral Testosterone Undecanoate Softgel (JATENZO®)
Date/time: Monday, June 13, 2022, 12:30 p.m. – 2:30 p.m. ET
Session/location: PMON267, Hall A1

About Male Hypogonadism
Male hypogonadism is a condition that results when the testes do not produce enough testosterone. Symptoms associated with male hypogonadism can include depression, decreased sex drive, decreased muscle mass, and decreased bone density, among others. An estimated 20 million men in the United States have hypogonadism, with approximately six million patients diagnosed. Treatments for male hypogonadism may include testosterone replacement therapy.

About Clarus Therapeutics Holdings, Inc.
Clarus Therapeutics Holdings, Inc. is a pharmaceutical company with expertise in developing androgen and metabolic therapies for men and women – including potential therapies for orphan indications. Clarus' first commercial product is JATENZO® (testosterone undecanoate). For more information, visit www.clarustherapeutics.com and www.jatenzo.com. Follow us on Twitter (@Clarus_Thera) and LinkedIn (Clarus Therapeutics).

JATENZO® is a registered trademark of Clarus Therapeutics Holdings, Inc.

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About JATENZO

Indication
JATENZO® (testosterone undecanoate) capsules, CIII, is an androgen indicated 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 cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter 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.

Limitation of use
Safety and efficacy of JATENZO in males less than 18 years old have not been established.

IMPORTANT SAFETY INFORMATION

WARNING: INCREASES IN BLOOD PRESSURE

- **JATENZO can cause blood pressure (BP) increases that can increase the risk of major adverse cardiovascular events (MACE), including non-fatal myocardial infarction, non-fatal stroke and cardiovascular death.**

- **Before initiating JATENZO, consider the patient's baseline cardiovascular risk and ensure blood pressure is adequately controlled.**
- **Periodically monitor for and treat new-onset hypertension or exacerbations of pre-existing hypertension and re-evaluate whether the benefits of JATENZO outweigh its risks in patients who develop cardiovascular risk factors or cardiovascular disease on treatment.**
- **Due to this risk, use JATENZO only for the treatment of men with hypogonadal conditions associated with structural or genetic etiologies.**

CONTRAINDICATIONS

JATENZO is contraindicated in men with breast cancer or known or suspected prostate cancer. JATENZO is contraindicated in women who are pregnant as testosterone may cause fetal harm.

WARNINGS AND PRECAUTIONS

- Check hematocrit prior to initiation and every 3 months while a patient is on JATENZO and if hematocrit becomes elevated, stop JATENZO until hematocrit decreases to an acceptable level. If hematocrit increases after JATENZO is restarted, stop permanently.
- Monitor patients with benign prostatic hyperplasia (BPH) treated with androgens due to an increased risk for worsening signs and symptoms of BPH.
- Venous thromboembolic events (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), have been reported in patients using testosterone replacement products like JATENZO. Evaluate patients with signs or symptoms consistent with DVT or PE and, if a VTE is suspected, discontinue JATENZO and initiate appropriate workup and management.
- Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids.
- Large doses of androgens can suppress spermatogenesis by feedback inhibition of pituitary FSH. Inform patients of this risk before prescribing JATENZO.
- Prolonged use of high doses of methyltestosterone has been associated with serious hepatic adverse events. JATENZO is not known to cause these adverse events; however, patients should be instructed to report any signs of hepatic dysfunction and JATENZO should be discontinued while the cause is evaluated.
- Edema, with or without congestive heart failure, may be a serious complication in patients with pre-existing cardiac, renal, or hepatic disease. In addition to discontinuation of the drug, diuretic therapy may be required.
- Gynecomastia may develop and persist in patients being treated for hypogonadism.
- Sleep apnea may occur in some patients, especially those with risk factors such as obesity or chronic lung disease.
- Changes in the serum lipid profile may require dose adjustment of lipid-lowering drugs or discontinuation of testosterone therapy. Monitor the lipid profile periodically, particularly after starting testosterone therapy.
- Use JATENZO with caution in cancer patients at risk of hypercalcemia. Monitor serum calcium concentration regularly during treatment with JATENZO in these patients.
- Androgens, including JATENZO, may decrease concentrations of thyroxine-binding globulin, resulting in decreased total T4 serum concentrations and increased resin uptake of T3 and T4. Free thyroid hormone concentrations remain unchanged, however, and there is no clinical evidence of thyroid dysfunction.
- Depression and suicidal ideation have been reported in patients treated with JATENZO in clinical trials.

ADVERSE EVENTS

The most common adverse events of JATENZO (incidence ≥2%) are headache (5%), increased hematocrit (5%), hypertension (4%), decreased HDL (3%), and nausea (2%).

These are not all of the risks associated with JATENZO. For more information, click here for full Prescribing Information, including BOXED WARNING on increases in blood pressure. You can also obtain information regarding JATENZO at www.jatenzo.com.