Akrimax Pharmaceuticals Announces Sponsorship of the 15th International Thyroid Congress

Symposium will educate attendees on T4/T3 therapy treatment for hypothyroidism

Cranford, NJ (June, 2015) – Akrimax Pharmaceuticals, LLC, a privately held, innovative specialty pharmaceutical company, today announced that it will co-sponsor a CME symposium at this year’s 15th International Thyroid Congress (ITC). The ITC is a convention held every five years, hosted by four thyroid associations known worldwide: American Thyroid Association (ATA), Asia-Oceania Thyroid Association, European Thyroid Association, and Latin American Thyroid Society. The ATA and the University of Colorado School of Medicine are jointly responsible for hosting the 15th ITC Continuing Medical Education. The University of Colorado School of Medicine is officially recognized by the Accreditation Council for Continuing Medical Education to continue to educate medical physicians.

Akrimax and Institut Biochimique SA (IBSA) will jointly sponsor the symposium called “T4/T3 Therapy” on October 19th at 1:50 pm. During the symposium, Dr. Colin M. Dayan, Director of the Institute of Molecular & Experimental Medicine at Cardiff University, will be discussing why patients prefer T4/T3 therapy. Chair of the Division of Endocrinology and Metabolism at Virginia Commonwealth University, Dr. Francesco Celi, will review the mechanism for enhanced weight loss with T3. The risks and benefits of combination therapy will be explained by Dr. Anne R. Cappola, an Associate Professor of Medicine in the Division of Endocrinology, Diabetes, and Metabolism at the Perelman School of Medicine at the University of Pennsylvania.

Dr. Keith Rotenberg, Corporate Vice President and Chief Scientific Officer of Akrimax Pharmaceuticals, stated, “Akrimax is proud to sponsor the 15th International Thyroid Congress and the continuation of medical education. We hope that the 15th ITC will further inform physicians on new medical findings and help them to better manage patient care. We believe that Tirosint® (levothyroxine sodium) capsules provide unique benefits for T4 therapy treatment and are excited to share these important benefits to help millions of patients suffering from hypothyroidism.”

Akrimax and IBSA are planning to exhibit at the conference. Akrimax will have an exhibit alongside IBSA, the manufacturers of Tirosint®, which will provide information to educate healthcare professionals attending ITC on the use of Tirosint® for patients with hypothyroidism.

The 15th ITC will take place from October 18th to the 23rd at the Walt Disney World Swan and Dolphin Resort in Lake Buena Vista, Florida.

About Hypothyroidism

Hypothyroidism is an endocrine disorder with numerous causes resulting in a deficiency in thyroid hormone. About 2% of the U.S. population has pronounced hypothyroidism, and as
much as 10% has subclinical (mild) hypothyroidism. Up to 13 million Americans have undiagnosed hypothyroidism. The condition is most common in women over 40 years of age and in the elderly of both sexes. The signs and symptoms of hypothyroidism are nonspecific and may include fatigue, cold intolerance, coarse hair, dry skin, weight gain, delayed return phase of reflexes, and constipation. Laboratory tests (TSH, FT3 and FT4) are the most common way hypothyroidism is detected. Treatment with levothyroxine sodium oral tablets is the standard of care in hypothyroidism.

**About Tirosint® (levothyroxine sodium) capsules**

Tirosint® (levothyroxine sodium) is the first and only levothyroxine therapy in a liquid gel cap. Tirosint® gel caps are pure. Tirosint® gel caps contain only T4, water, glycerin, and gelatin.

Tirosint® is available in 10 dosage strengths, including an exclusive 13 microgram dose. Tirosint® is administered as a single daily dose, preferably one-half to one-hour before breakfast. Tirosint® should be taken at least 4 hours apart from drugs that are known to interfere with its absorption. Tirosint® capsules cannot be cut or crushed. Due to the long half-life of levothyroxine, the peak therapeutic effect at a given dose of levothyroxine sodium may not be attained for 4-6 weeks.

Tirosint® capsules are housed in blister packs to protect it from light and moisture. Blister packs are clearly marked for daily dosing. Tirosint® should be protected from light and moisture and stored at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F).

**IMPORTANT SAFETY INFORMATION**

**WARNINGS**

Thyroid hormones, including Tirosint®, either alone or with other therapeutic agents, should not be used for the treatment of obesity or for weight loss. In euthyroid patients, doses within the range of daily hormonal requirements are ineffective for weight reduction. Larger doses may produce serious or even life threatening manifestations of toxicity, particularly when given in association with sympathomimetic amines such as those used for their anorectic effects.

In patients with nontoxic diffuse goiter or nodular thyroid disease, particularly the elderly or those with underlying cardiovascular disease, levothyroxine sodium therapy is contraindicated if the serum TSH level is already suppressed due to the risk of precipitating overt thyrotoxicosis. If the serum TSH level is not suppressed, Tirosint® should be used with caution in conjunction with careful monitoring of thyroid function for evidence of hyperthyroidism and clinical monitoring for potential associated adverse cardiovascular signs and symptoms of hyperthyroidism.

**CONTRAINDICATIONS**

Levothyroxine is contraindicated in patients with untreated subclinical (suppressed serum TSH level with normal T3 and T4 levels) or overt thyrotoxicosis of any etiology and in patients with acute myocardial infarction. Levothyroxine is contraindicated in patients with uncorrected adrenal insufficiency since thyroid hormones may precipitate an acute adrenal crisis by increasing the metabolic clearance of glucocorticoids. Tirosint® is contraindicated in patients with hypersensitivity to any of the inactive ingredients in Tirosint® capsules. Tirosint® is also contraindicated for anyone who may be unable to swallow a capsule (e.g., infants, small children).
PRECAUTIONS

Effects on bone mineral density – In women, long-term levothyroxine sodium therapy has been associated with increased bone resorption, thereby decreasing bone mineral density, especially in postmenopausal women on greater than replacement doses or in women who are receiving suppressive doses of levothyroxine sodium. The increased bone resorption may be associated with increased serum levels and urinary excretion of calcium and phosphorous, elevations in bone alkaline phosphatase and suppressed serum parathyroid hormone levels. Therefore, it is recommended that patients receiving levothyroxine sodium be given the minimum dose necessary to achieve the desired clinical and biochemical response.

Patients with underlying cardiovascular disease – Exercise caution when administering levothyroxine to patients with cardiovascular disorders and to the elderly in whom there is an increased risk of occult cardiac disease. In these patients, levothyroxine therapy should be initiated at lower doses than those recommended in younger individuals or in patients without cardiac disease and it should be noted that unlike levothyroxine sodium tablets, Tirosint® capsules cannot be cut in half. If cardiac symptoms develop or worsen, the levothyroxine dose should be reduced or withheld for one week and then cautiously restarted at a lower dose. Overtreatment with levothyroxine sodium may have adverse cardiovascular effects such as an increase in heart rate, cardiac wall thickness, and cardiac contractility and may precipitate angina or arrhythmias. Patients with coronary artery disease who are receiving levothyroxine therapy should be monitored closely during surgical procedures, since the possibility of precipitating cardiac arrhythmias may be greater in those treated with levothyroxine. Concomitant administration of levothyroxine and sympathomimetic agents to patients with coronary artery disease may precipitate coronary insufficiency.

ADVERSE REACTIONS

Adverse reactions associated with levothyroxine therapy are primarily those of hyperthyroidism due to therapeutic overdosage such as fatigue, increased appetite, weight loss, heat intolerance, fever, excessive sweating, and other adverse reactions. This is not an exhaustive list. Please refer to Tirosint®’s full Prescribing Information for a more comprehensive list of adverse reactions associated with hyperthyroidism.

About Akrimax Pharmaceuticals

Akrimax Pharmaceuticals, LLC is a privately held, innovative specialty pharmaceutical company that acquires, develops and markets advanced ethical prescription medications. Akrimax’s marketed products include: Primlev™ (oxycodone hydrochloride/acetaminophen) CII, Tirosint® (levothyroxine sodium) capsules, NitroMist® (nitroglycerin lingual aerosol), Inderal LA® (propranolol hydrochloride) long-acting capsules and InnoPran XL® (propranolol hydrochloride) extended-release capsules. In order to bring the best treatments to patients, Akrimax is continuously evaluating opportunities to partner with other organizations that strive to improve patient care. For more information, visit www.akrimax.com.

References


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