RECORDATI RARE DISEASES GROUP

NEWS RELEASE

RECORDATI RARE DISEASES ANNOUNCES MULTIPLE SCIENTIFIC ABSTRACTS TO BE HIGHLIGHTED AT AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGY

Lebanon, NJ, May 10, 2022 – Recordati Rare Diseases Inc. announced today that various scientific abstracts have been accepted and will be featured onsite at the American Association of Clinical Endocrinology (AACE) annual meeting being held in San Diego, California from May 12 – 14, 2022. Recordati will be exhibiting at booth #122.

Key Onsite abstracts presented by Alberto Pedroncelli MD, Head of Clinical Development & Medical Affairs, Global Endocrinology, Recordati AG. All times listed are in Pacific Daylight Time (PDT).

- **Oral presentation Thursday, May 12, 2022 1:30 PM – 1:50 PM**
  Osilodrostat Therapy Improves Physical Features Associated with Hypercortisolism in Patients with Cushing's Disease: Findings from the Phase III LINC 3 Study*
  - *Abstract Authors: Rosario Pivonello MD, Maria Fleseriu MD, Akira Shimatsu MD, John Newell-Price MD, Richard J Auchus MD, Richard A Feelders MD, Alberto M Pedroncelli MD, Andrea Piacentini, Beverly MK Biller MD
- **Poster presentation, Friday, May 13, 2022 1:00 PM – 1:15 PM**
  Hypertension and Diabetes Improvement During Osilodrostat Therapy in Patients with Cushing's Disease: Analyses from the Phase III LINC 3 Study*
  - **Abstract Authors: Maria Fleseriu MD, Rosario Pivonello MD, John Newell-Price MD, Akira Shimatsu MD, Andre Lacroix MD, Richard J Auchus MD, Andrea Piacentini, Alberto M Pedroncelli MD, Beverly MK Biller MD

Additional Onsite Activity:

- **Kevin Yuen, MD - Friday May 13, 10:10 AM - 10:55 AM**
  Managing Patients with Cushing's Disease*
  Location: Learning Lab 'B', AACE Learning Zone
  Synopsis: In this product theater, Dr. Kevin Yuen from the Barrow Neurological Institute and Pituitary Center will review the pathogenesis and treatment of Cushing's Disease within the context of a patient case. He will also present clinical data from two Phase 3 trials of ISTURISA®(osilodrostat).
  - *This program is non-CME.

All educational content of the AACE annual meeting is planned by its program committee, and AACE does not endorse, promote, approve, or recommend the use of any products, devices or services.

Important Safety Information for ISTURISA

Indications and usage

ISTURISA (osilodrostat) is a cortisol synthesis inhibitor indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Warnings and precautions

- **Hypocortisolism:** ISTURISA lowers cortisol levels and can lead to hypocortisolism and sometimes life-threatening adrenal insufficiency. Lowering of cortisol can cause nausea, vomiting, fatigue, abdominal pain, loss of appetite, and dizziness. Significant lowering of serum cortisol may result in hypotension, abnormal electrolyte levels, and hypoglycemia.

  Hypocortisolism can occur at any time during ISTURISA treatment. Evaluate patients for precipitating causes of hypocortisolism (infection, physical stress, etc). Monitor 24-hour urinary free cortisol, serum or plasma cortisol, and patient's signs and symptoms periodically during ISTURISA treatment.

  Decrease or temporarily discontinue ISTURISA if urinary free cortisol levels fall below the target range, there is a rapid decrease in cortisol levels, and/or patients report symptoms of hypocortisolism. Stop ISTURISA and administer exogenous glucocorticoid replacement therapy if serum or plasma cortisol levels are below target range and patients have symptoms of adrenal insufficiency. After ISTURISA discontinuation, cortisol suppression may persist beyond the 4-hour half-life of ISTURISA. Please see section 5.1 of full Prescribing Information.

  Educate patients on the symptoms associated with hypocortisolism and advise them to contact a healthcare provider if they occur.

- **QTc prolongation:** ISTURISA is associated with a dose-dependent QT interval prolongation, which may cause cardiac arrhythmias. Perform an ECG to obtain a baseline QTc interval measurement prior to initiating therapy with ISTURISA and monitor for an effect on the QTc interval thereafter. Correct hypokalemia and/or hypomagnesemia prior to ISTURISA initiation and monitor periodically during treatment with ISTURISA. Use with caution in patients with risk factors for QT prolongation and consider more frequent ECG monitoring. Please see section 5.2 of full Prescribing Information.

- **Elevations in adrenal hormone precursors and androgens:** ISTURISA blocks cortisol synthesis and may increase circulating levels of cortisol and aldosterone precursors and androgens. This may activate mineralocorticoid receptors and cause hypokalemia, edema and hypertension. Hypokalemia should be corrected prior to initiating ISTURISA. Monitor patients treated with ISTURISA for hypokalemia, worsening of hypertension and edema. Inform patients of the symptoms associated with hyperandrogenism and advise them to contact a healthcare provider if they occur. Please see section 5.3 of full Prescribing Information.

Adverse reactions

- Most common adverse reactions (incidence >20%) are adrenal insufficiency, fatigue, nausea, headache, and edema.
- **To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Drug interactions

- **CYP3A4 inhibitor:** Reduce the dose of ISTURISA by half with concomitant use of a strong CYP3A4 inhibitor.

- **CYP3A4 and CYP2B6 inducers:** An increase of ISTURISA dosage may be needed if ISTURISA is used concomitantly with strong CYP3A4 and CYP2B6 inducers. A reduction in ISTURISA dosage may be needed if strong CYP3A4 and CYP2B6 inducers are discontinued while using ISTURISA.

Use in specific populations

- **Lactation:** Breastfeeding is not recommended during treatment with ISTURISA and for at least 1 week after treatment.

Please refer to full Prescribing Information.

About Cushing's disease

Cushing's disease is a form of Cushing's syndrome, in which chronically elevated cortisol levels is triggered by a pituitary adenoma secreting excess adrenocorticotropic hormone (ACTH). It is a rare, serious and difficult-to-treat disease that affects approximately one to two patients per million per year. Prolonged exposure to elevated cortisol levels is associated with considerable morbidity, mortality and impaired QoL as a result of complications and comorbidities. Normalization of cortisol levels is therefore a primary objective in the treatment of Cushing's disease.

About ISTURISA

ISTURISA is a cortisol synthesis inhibitor that works by inhibiting 11-beta-hydroxylase, an enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. ISTURISA is available as 1 mg, 5 mg and 10 mg film-coated tablets. Please see prescribing information for detailed recommendations for the use of this product. In March 2020, the FDA granted marketing authorization for ISTURISA in the United States. For more information visit www.isturisa.com

About Recordati Rare Diseases Inc.

Recordati Rare Diseases Inc. is a biopharmaceutical company committed to providing often-overlooked orphan therapies to the underserved rare disease communities of the United States.

Recordati Rare Diseases is a part of the Recordati Group, a public international specialty pharmaceutical company committed to the research and development of new specialties with a focus on treatments for rare diseases. Recordati Rare Diseases' mission is to reduce the impact of extremely rare and devastating diseases by providing urgently needed therapies. We work side-by-side with rare disease communities to increase awareness, improve diagnosis and expand availability of treatments for people with rare diseases.

The company's U.S. corporate headquarters is located in Lebanon, NJ, with global headquarter offices located in Milan, Italy. https://www.recordatirarediseases.com/us

For a full list of products, please click here: www.recordatirarediseases.com/us/products

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