NEWS RELEASE

RECORDATI RARE DISEASES INC. ANNOUNCES AVAILABILITY OF ISTURISA® (OSILODROSTAT) IN THE UNITED STATES

ISTURISA® (osilodrostat) Is Now Exclusively Available Through AnovoRx Specialty Pharmacy. In An Effort To Increase Patient Access To ISTURISA, Recordati Rare Diseases Has Established the R.A.R.E. Patient Support Program.

Lebanon, NJ, May 27, 2020 – Recordati Rare Diseases Inc. announced today the full availability of ISTURISA® (osilodrostat) for sale and distribution in the United States. ISTURISA was approved by the US Food and Drug Administration (FDA) on March 6, 2020, for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. It is the first and only FDA-approved inhibitor of 11-beta-hyrdoxylase that has demonstrated normalization of cortisol levels in a significant portion of adult patients, and is associated with a manageable safety profile.

ISTURISA will be available exclusively through the R.A.R.E.™ (Recordati, Access, Resources, and Engagement) Patient Support Program, an initiative created by Recordati in partnership with Anovo, a specialty pharmacy dedicated to serving patients with rare and chronic conditions. In addition to prescription fulfillment, the R.A.R.E Patient Support Program will provide insurance benefits investigation, educational support, resources for qualified patients to obtain financial assistance and other services designed to help patients access treatment. To enroll patients in the program and prescribe ISTURISA, clinicians will need to complete a patient referral form available at www.isturisastart.com.

"ISTURISA is a meaningful addition to the treatment options for Cushing's disease and helps address the significant unmet need for patients affected by this rare and life-threatening disease," said Richard J. Auchus MD, PhD, a Professor of Medicine at the University of Michigan School of Medicine. "ISTURISA mechanistically inhibits the final step of the cortisol synthesis pathway. Achieving control of cortisol production is an important strategy to help patients manage Cushing's disease, and it may be crucial for mitigating the risk for comorbidities associated with hypercortisolism."

The FDA approval was based on evidence from the Phase 3 clinical program including the LINC-3 study, which met its primary endpoint after demonstrating that a significantly higher proportion of patients treated with ISTURISA maintained normal mean urinary free cortisol (mUFC) at the end of the 8-week randomized withdrawal period (week 34) versus patients switched to placebo (86% vs 29%). Adverse drug reactions associated with ISTURISA and occurring in greater than 20% of patients included adrenal insufficiency, fatigue, nausea, headache and edema. ISTURISA is available in 1 mg, 5 mg and 10 mg tablet options,

thus allowing clinicians greater flexibility for individualizing dosing for each patient's unique needs.

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-hr urine free cortisol, serum or plasma cortisol, and patient's signs and symptoms periodically during ISTURISA treatment.

  Decrease or temporarily discontinue ISTURISA if urine 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 one 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 excess cortisol production is triggered by a pituitary adenoma secreting excess adrenocorticotropic hormone (ACTH). It is a rare but serious disease that affects approximately one to two patients per million per year. Cushing's disease most commonly affects adults as young as 20 to 50 years and affects women three times more often than men. It may present with weight gain, central obesity, a round, red full face, severe fatigue and weakness, striae (purple stretch marks), high blood pressure, depression and anxiety. Cushing's disease can cause severe illness and death with mortality up to four times higher than in the healthy population.

About ISTURISA®
ISTURISA is a cortisol synthesis inhibitor that works by preventing 11-betahydroxylase, an enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland, from being created. 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 January 2020, the European Commission granted marketing authorization for ISTURISA in the European Union (EU). 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 part of the Recordati Group, a public international 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.

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

For additional information, please visit our website: https://www.recordatirarediseases.com/us

Company Contact
Alan Erck
Vice President, Commercial Operations
(908) 377-9000
e-mail: erck.a@recordati.com

Media Contact
Cassandra Dump
Pascale Communications for Recordati
(619) 971-1887
e-mail: cassy@pascalecommunications.com

Statements contained in this release, other than historical facts, are "forward-looking statements" (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are based on currently available information, on current best estimates, and on assumptions believed to be reasonable. This information, these estimates and assumptions may prove to be incomplete or erroneous, and involve numerous risks and uncertainties, beyond the Company's control. Hence, actual results may differ materially from those expressed or implied by such forward-looking statements. All mentions and descriptions of Recordati products are intended solely as information on the general nature of the company's activities and are not intended to indicate the advisability of administering any product in any particular instance.

PP-IST-US-0045