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NEWS RELEASE

RECORDATI: ISTURISA® (OSILODROSTAT) PHASE III LINC-4 TRIAL MEETS ITS PRIMARY ENDPOINT IN CUSHING'S DISEASE

Isturisa® (osilodrostat) demonstrates significant and sustained benefit over placebo at normalizing mean urinary free cortisol (mUFC) levels in patients with Cushing's disease

Milan, 17 June 2020 – Recordati today announces positive results from the large Phase III LINC-4 study of Isturisa® (osilodrostat) for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Data from the LINC-4 study demonstrate that a significantly higher proportion of patients receiving Isturisa® achieve normal mUFC, the primary treatment goal for Cushing's disease, after 12 weeks of treatment versus placebo (77% vs 8%; *P*<0.0001). Improvements in mUFC levels are sustained over 36 weeks of treatment (81% of patients). Isturisa® is well tolerated and has a manageable safety profile, with the most common adverse events in LINC-4 being arthralgia, decreased appetite, fatigue, and nausea. The findings from LINC-4, the first Phase III study of a medical therapy in Cushing's disease to contain an upfront placebo-controlled phase, builds on existing clinical evidence and affirms the effectiveness of Isturisa® in this hard-to-treat patient population.[1-3]

"Cushing's disease is a chronic and debilitating condition that can be extremely challenging to manage and, if left inadequately treated, can have a significant impact on patients' quality of life and increase the risk of mortality", said Richard Feelders, MD, Professor of Endocrinology at the Erasmus University Medical Centre, Rotterdam. "Data from this important Phase III study show that Isturisa® (osilodrostat) is an effective and well-tolerated therapy for Cushing's disease, which significantly reduces and normalizes mUFC levels in most patients. These data are encouraging given the high unmet medical need for patients with this rare disorder".

"The compelling topline LINC-4 data confirm the effectiveness of Isturisa® for the treatment of this rare, potentially life-threatening disease", stated Andrea Recordati, CEO. "We are deeply grateful to the patients, investigators, clinicians and study staff whose ongoing participation in the clinical development of Isturisa® has helped bring this therapy to patients in need."

Data from the LINC 4 study reinforce the clinical benefits of Isturisa® as an effective and generally well-tolerated oral treatment option for patients with Cushing's disease. Isturisa® has recently received marketing authorization in the European Union (January 2020) and United States (March 2020) for the treatment of Cushing's syndrome and Cushing's disease, respectively.

About Cushing's syndrome

Cushing's syndrome is caused by an inappropriate and chronic exposure to excessive levels of cortisol. The source of this excess of cortisol can be endogenous or exogenous (ie medication). When the excess cortisol production is triggered by a pituitary adenoma (ie a tumor of the pituitary gland located in the brain) secreting excess adrenocorticotropic hormone (ACTH), the condition of the patient is defined as Cushing's disease and comprises about 70% of Cushing's syndrome cases.[4] It is a rare, serious and difficult-to-treat disease that affects approximately one to two patients per million per year.[5] Prolonged exposure to elevated cortisol levels is associated with considerable morbidity, mortality and

impaired quality of life as a result of complications and comorbidities.[6] Normalization of cortisol levels is therefore a primary objective in the treatment of Cushing's syndrome.[7]

About LINC-4

LINC-4 is a large randomized, double-blinded, multicentre, 48-week trial with an initial 12-week placebo-controlled period to evaluate the safety and efficacy of osilodrostat in patients with Cushing's disease. The primary endpoint in the LINC-4 trial is the proportion of patients randomized to Isturisa® and placebo, separately, with a mUFC ≤ULN at the end of the 12-week placebo-controlled period. The key secondary endpoint is the proportion of patients in both arms combined with a mUFC ≤ULN after 36 weeks. LINC-4 involved 73 patients with persistent or recurrent Cushing's disease or those with *de novo* disease who were not candidates for surgery.

About Isturisa®

Isturisa® is a potent oral, reversible inhibitor of 11β-hydroxylase (CYP11B1), the enzyme that catalyses the final step of cortisol biosynthesis in the adrenal gland and is authorized in the EU and US for the treatment of adult patients with Cushing's syndrome and Cushing's disease, respectively.[8,9] Isturisa® will be 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.[8,9]

1. Bertagna X *et al. J Clin Endocrinol Metab* 2014;99:1375–83
2. Fleseriu M *et al. Pituitary* 2016;19:138–48
3. Biller BMK *et al.* Abstract OR16-2. Oral presentation at the Endocrine Society Annual Congress 2019
4. Nieman LK *et al. Am J Med* 2005;118:1340–6
5. Signifor® and Signifor® LAR Summary of Product Characteristics, June 2018
6. Pivonello R *et al. Lancet Diabetes Endocrinol* 2016;4:611–29
7. Nieman LK *et al. J Clin Endocrinol Metab* 2015;100:2807–31
8. Isturisa® Summary of Product Characteristics. May 2020
9. Isturisa® Prescribing Information. March 2020

About the Recordati group

***Recordati**, established in 1926, is an international pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of more than 4,300, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations throughout the whole of Europe, including Russia, Turkey, North Africa, the United States of America, Canada, Mexico, some South American countries, Japan and Australia. An efficient field force of medical representatives promotes a wide range of innovative pharmaceuticals, both proprietary and under license, in a number of therapeutic areas including a specialized business dedicated to treatments for rare diseases. Recordati is a partner of choice for new product licenses for its territories. Recordati is committed to the research and development of new specialties with a focus on treatments for rare diseases. Consolidated revenue for 2019 was € 1,481.8 million, operating income was € 465.3 million and net income was € 368.9 million.*

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