NEWS RELEASE

RECORDATI RARE DISEASES ANNOUNCES FIRST EUROPEAN LAUNCH OF ISTURISA® (OSILODROSTAT)

Isturisa® (osilodrostat), a novel treatment for Cushing's Syndrome, is now commercially available in France, and will be across select other European Union markets over 2020.

Puteaux, France, June 2, 2020 – Recordati Rare Diseases announced today the commercial availability of Isturisa® (osilodrostat). Over 50 patients with Cushing's syndrome have already been initiated on Isturisa® under temporary authorization for use (ATU), granted by the French National Agency for Medicines and Health Products Safety (ANSM), a special access scheme.

Isturisa®, indicated for the treatment of adult patients with endogenous Cushing's syndrome (CS), is now available in France as the first EU country to launch. Isturisa® was granted marketing authorization by the European Commission (EC) on 9thJanuary 2020.

"Isturisa® is a meaningful addition to the treatment options for Cushing's syndrome and helps address the unmet need of patients affected by this rare and debilitating disease," said Jacques Young, MD, PhD, Professor of Medicine at University Paris Saclay. "It is supported by data generated through prospective clinical trials within the development program of Isturisa®, providing robust evidence in terms of helping patients to achieve normal cortisol levels while also improving clinical signs and symptoms and their quality of life. Isturisa® is a new medication in our strategy of helping patients to manage Cushing's syndrome, and may be crucial for mitigating the risk of comorbidities associated with hypercortisolism."

The European Commission approval was based on data from the development program including the pivotal LINC-3 study, which met its primary endpoint by demonstrating that a significantly higher proportion of patients continued being treated with Isturisa®, maintained normal mean urinary free cortisol (mUFC) at the end of the 8-week randomized withdrawal period (week 34) compared with the ones switched to placebo (86% vs 29%). Adverse drug reactions associated with Isturisa® and occurring in more than 20% of patients included adrenal insufficiency, fatigue, nausea, headache and edema. There were no unexpected adverse events. Isturisa® will be made available in 1-, 5- and 10-mg tablet strengths, thus allowing clinicians great flexibility for individualizing patient dosing[1].

Professor Young further notes "we had the opportunity to benefit from Isturisa® as part of a special access scheme in France since April 2019. Response to the treatment has been extremely positive across the severity spectrum of Cushing's patients, even more so when I consider my patients that have switched from current treatment options."

The launch of Isturisa® is an addition to the Recordati Rare Diseases endocrinology portfolio which also includes Signifor® , subcutaneous and intramuscular formulations, available across Europe, indicated for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed, and for adult patients with acromegaly for whom surgery is not an option or has not been curative and who are inadequately controlled on treatment with another somatostatin analogue[2].

About Cushing's Syndrome

Cushing's syndrome (CS) 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 is about 70% of CS cases[3]. It is a rare but serious disease that affects approximately one to two patients per million per year[2]. Cushing's disease most commonly affects adults as young as 20 to 50 years old and affects women three times more often than men[4]. 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[2]. Cushing's disease can cause severe illness and death with mortality up to four times higher than in the healthy population[5].

About Isturisa®

Isturisa® is a potent inhibitor of 11β-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol synthesis in the adrenal gland. 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.

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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.

References

1.Isturisa® Summary of Product Characteristics. May 2020.
2. Signifor® and Signifor® LAR Summary of Product Characteristics, June 2018
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4. Sharma ST et al. Clin Epidemiol 2015;7:281
5. Gravesen D et al. Eur J Int Med 2012;23:278

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