

RECORDATI SUBMITS NEW DRUG APPLICATION FOR ISTURISA® IN JAPAN

Milan, 26 March 2020 – Recordati announces the submission of the Japanese New Drug Application (JNDA) to the Ministry of Health, Labour and Welfare seeking marketing approval for osilodrostat an oral inhibitor of 11-beta-hydroxylase for the treatment of patients with Cushing’s syndrome (CS).

The JNDA for osilodrostat is primarily based on data generated by the clinical program which included Japanese patients. In the Phase 3 LINC-3 study, a significantly higher proportion of patients treated with Isturisa® (osilodrostat) maintained normal mean urinary free cortisol (mUFC) at the end of the 8-week randomized withdrawal period (week 34) versus placebo (86.1% vs 29.4%). The safety profile was manageable.

“We are excited about this regulatory filing for osilodrostat in Japan which, if approved, will provide a new and convenient oral treatment option that will help address patients’ needs in this underserved patient population” said Andrea Recordati, CEO.

About Cushing’s Syndrome

Cushing’s syndrome is a rare, chronically debilitating, life-threatening condition. The primary clinical symptoms of Cushing’s syndrome are due to hypercortisolism and include the following: changes in body habits due to increased fat accumulation; hirsutism; skin changes with easy bruising, purplish striae, reddening and ulceration of the cheeks; generalized weakness and fatigue; wasting of musculature; menstrual disorders in females; decreased fertility and/or libido; hypertension; weight gain; increased insulin resistance with alterations in glucose metabolism; dyslipidemia; depression, mood and behavior disorders; sleep disturbances and osteopenia/osteoporosis.

Hypercortisolism is the main driving force of morbidity and mortality in patients with Cushing’s syndrome, therefore, potent inhibition of cortisol synthesis (and the resulting normalization of cortisol levels) has the potential to ameliorate the complications of this debilitating group of disorders.

About Isturisa®

Isturisa® (osilodrostat) 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. Given the mechanism of action to inhibit cortisol synthesis at the adrenal glands, osilodrostat has therapeutic potential in all forms of endogenous Cushing syndrome.

About Recordati Rare Diseases K.K.

Recordati Rare Diseases K.K. is a biopharmaceutical company committed to providing often-overlooked orphan therapies to the underserved rare disease communities in Japan. Recordati Rare Diseases is a part of the rare disease business within 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.

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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.

For a full list of our Japanese products please click here:
https://www.recordati.com/en/international_presence/japan

The company's Japanese headquarters is located in Tokyo, with global headquarter offices located in Milan, Italy.

About Recordati

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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