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NEWS RELEASE

RECORDATI: ISTURISA® (OSILODROSTAT) APPROVED

Milan, 15 January, 2020 – Recordati announces that the European Commission has granted marketing authorisation for the orphan medicinal product Isturisa® (osilodrostat), indicated for the treatment of endogenous Cushing's syndrome (CS) in adults. The active substance of Isturisa® is osilodrostat, a cortisol synthesis inhibitor. Osilodrostat works by inhibiting 11-beta-hydroxylase, an enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. Isturisa® will be available as 1-mg, 5-mg and 10-mg film-coated tablets.

The benefits of Isturisa® are its ability to control or normalise cortisol levels in adult CS patients with a manageable safety profile, making this product a valuable treatment option for patients with Cushing's syndrome.

The data generated throughout the clinical program show that osilodrostat leads to normalisation of cortisol levels in the majority of patients, as well as improvement in multiple clinical features of the disease and quality of life, thereby providing significant clinical benefit in an area with unmet medical need. Particularly, in the LINC-3 study a significantly higher proportion of patients in the Isturisa® arm maintained normal mUFC at the end of the 8-week randomised withdrawal period (week 34) versus placebo (86.1% vs 29.4%). Cortisol level control is the primary objective in the treatment of Cushing's patients.

The EC decision also confirmed the Orphan status of Isturisa® providing 10 years of market exclusivity.

Detailed recommendations for the use of this product are described in the summary of product characteristics (SmPC), published in the European public assessment report (EPAR) and made available in all official European Union languages.

"We are very pleased with the approval of Isturisa® (osilodrostat) by the European Commission", declared Andrea Recordati, CEO. "Recordati Rare Diseases is committed to making this innovative treatment available for all patients suffering from endogenous Cushing's syndrome worldwide and the European approval and subsequent launch is an important first step in this direction".

Recordati recently acquired the worldwide rights to Isturisa® (osilodrostat) from Novartis.

***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 4,100, 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 2018 was € 1,352.2 million, operating income was € 442.2 million and net income was € 312.4 million.*

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