

RECORDATI: CHMP ADOPTS POSITIVE OPINION FOR ISTURISA® (OSILODROSTAT)

Milan, 15 November 2019 – Recordati announces that the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Isturisa®, indicated for the treatment of endogenous Cushing's syndrome in adults. The benefits with Isturisa® are its ability to control or normalise raised cortisol levels. 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.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

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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