RECORDATI TO ACQUIRE WORLDWIDE RIGHTS TO SIGNIFOR® AND OSILODROSTAT (LCI699)

Milan, 12 July 2019 – Recordati announces the signing of an agreement with Novartis for the acquisition of worldwide rights to Signifor® and Signifor® LAR® for the treatment of Cushing’s disease and acromegaly in adult patients for whom surgery is not an option or for whom surgery has failed. Worldwide sales of Signifor® in 2018 were $ 72 million. The agreement also covers the acquisition of worldwide rights to osilodrostat (LCI699), an investigational innovative drug for the treatment of endogenous Cushing’s syndrome, for which marketing authorization applications have been filed in the European Union and in the USA.

Upon completion of the transaction a consideration of $ 390 million will be due to Novartis. Subsequently, additional milestone payments contingent upon the approval and market access of osilodrostat as well as royalties on sales of this new product, will be due. Under the terms of the agreement Novartis will supply these products to Recordati for a transitional period. At closing, the consideration will be funded by existing liquidity and new debt facilities. The closing of the transaction is subject to customary conditions and regulatory clearances and is expected to take place in few months.

Within Cushing’s syndrome (CS), Cushing’s disease (CD) is a severe endocrine disease caused by a pituitary adenoma, an enlargement in the pituitary gland which results in over-production of cortisol by the adrenal glands. Other causes of endogenous Cushing’s syndrome include rarer conditions such as adrenal adenoma, ectopic corticotropin syndrome and ACTH independent macronodular adrenal hyperplasia. This condition is associated with increased morbidity and mortality. Acromegaly is caused by an overexposure to growth hormone that leads to the production of insulin-like growth factor-1. The most common cause of acromegaly is a pituitary adenoma.

Signifor® contains the active substance pasireotide, a somatostatin analogue. The human body naturally produces somatostatin, which blocks the production and release of certain hormones, including ACTH. Pasireotide works in a very similar way to somatostatin. Signifor® is thus able to block the production of ACTH, helping to control the over-production of cortisol and improve the symptoms of Cushing’s disease.

Osilodrostat is an orally administered steroidogenesis inhibitor of 11Beta-hydroxylation, an enzyme which catalyses the final step of cortisol synthesis in the adrenal cortex. This new drug for endogenous Cushing’s syndrome is expected to represent an effective new treatment option for patients.

“We are extremely pleased with the agreement reached with Novartis for the acquisition of the rights to Signifor® and osilodrostat, fundamental treatments for patients suffering from Cushing’s disease and acromegaly and for whom surgery is not a viable solution,” declared Andrea Recordati,
CEO. “These important additions to our product portfolio of treatments for severe rare diseases represent a key and historical milestone for Recordati, reaffirming the continuation of the successful execution of its strategy to become a true global player in the treatment of rare diseases and to continue providing innovative therapeutic solutions for patients with rare serious conditions and unmet medical needs, which is the core of our mission,” concluded Andrea Recordati.

Jefferies served as Recordati’s financial advisor for the deal.

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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