

RECORDATI RECEIVES ORPHAN DRUG DESIGNATION FOR ITS INVESTIGATIONAL TREATMENT FOR NEUROTROPHIC KERATITIS

Milan, 5 December 2018 – Recordati today announced that the FDA has granted Orphan Drug Designation to Recordati Rare Disease's investigational product REC 0559 for the treatment of neurotrophic keratitis.

REC 0559 is a low molecular weight non-peptidic human nerve growth factor (NGF) mimetic currently under global development by Recordati. REC 0559 was licensed in 2017 from MimeTech, an Italian-based company focused on the development of pharmaceutical applications for synthetic neurotrophin mimetics.

Neurotrophic keratitis is a rare degenerative corneal disease, which in its more severe forms affects less than one person out of 10,000 worldwide, and it results from deficiency of the trigeminal nerve or its branches, usually caused by surgery, neoplasia, aneurysm or facial trauma. Impairment or loss of corneal sensory innervation is responsible for corneal epithelial defects, ulcer and perforation, with progression of the disease leading to dramatic impairment to patients' sight.

Orphan drug designation applies to drugs that seek to treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. while providing significant therapeutic advantage over existing therapies. The designation can provide development and commercial incentives for designated compounds and medicines, including eligibility for a seven-year period of market exclusivity in the U.S. after product approval, FDA assistance in clinical trial design and an exemption from FDA user fees.

“Orphan drug designation is a key regulatory achievement in the global development of REC 0559. We are very pleased to receive the designation from US FDA, which confirms our continuous commitment to innovative treatments to address the needs of patients suffering from rare diseases”, stated Andrea Recordati, CEO. “This represents another significant step in the development of our business dedicated to the treatment of diseases with unmet medical needs.”

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 2017 was € 1,288.1 million, operating income was € 406.5 million and net income was € 288.8 million.

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