

RECORDATI: LICENSE OBTAINED FOR THE COMMERCIALIZATION OF ELIGARD IN EUROPE AND OTHER COUNTRIES

Milan, 29 January 2021 – Recordati announces the closing of a License and Supply Agreement with Tolmar International Ltd, to commercialise Eligard® (leuprorelin acetate), in Europe, Turkey, Russia and other countries. Eligard® is a marketed medicinal product for the treatment of hormone dependent advanced prostate cancer and for the treatment of high-risk localized and locally advanced hormone dependent prostate cancer in combination with radiotherapy.

The active ingredient of Eligard® is leuprorelin acetate, a powder which is solubilized with a solvent for subcutaneous injection. Eligard® is available in three different dosages (for 1-month, 3-month and 6-month treatment, respectively) as a single kit containing two syringes. The development of a new device to administer the product which is easier to handle is currently ongoing, following the request from EMA. The regulatory variation is expected to be submitted by 31 October 2021.

The product has been commercialized by Astellas in the territories licensed to Recordati, with annual sales in the region of approximately € 100 million. Tolmar will manufacture the product for Recordati, while Astellas will provide to Recordati certain transitional services for an agreed period of time. Recordati will make an upfront payment of € 35 million to Tolmar which will also be eligible to receive additional milestone payments up to a total of € 105 million as well as royalties on sales.

“We are very pleased with the agreement reached with Tolmar which provides Recordati with a new product that strengthens our presence in the urological area and fits very well with our geographical footprint. Eligard® is a well-established medication that addresses a life-threatening disease with a high incidence in the population aged over 65 years and Recordati is committed to provide continuing support to patients and doctors in this field.”, declared Andrea Recordati, CEO. “We also wish to recognize the role that Astellas had in making the product available to the patients so far and for its willingness to cooperate with Recordati and Tolmar so that patients can continue to benefit from this important treatment with no interruption”.

Tolmar International, along with its U.S. affiliated companies, is a fully integrated pharmaceutical company focused on the innovative development, manufacturing, and commercialization of specialty pharmaceuticals. Tolmar International is headquartered in Ireland with manufacturing sites in the U.S.

Astellas Pharma Inc. based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information website astellas.com/eu.

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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