

## **RECORDATI AND HELSINN AGREEMENT FOR THE EXCLUSIVE COMMERCIALIZATION RIGHTS TO LEDAGA®**

**Milan and Lugano, December 20, 2018** – Recordati and Helsinn announce the signing of a license agreement between Orphan Europe, a Recordati group company dedicated to providing treatment for patients with unmet medical needs suffering from rare diseases, and Helsinn, a Swiss pharmaceutical group focused on building quality cancer care products, granting Orphan Europe exclusive rights to Ledaga® worldwide, excluding the United States, China, Hong Kong and Israel. The product has been granted Orphan Drug Designation in Europe and is approved by the European Commission subject to post approval commitments. Under the terms of the license agreement Orphan Europe will obtain the rights to market, promote and distribute Ledaga® in the designated territories and Helsinn will retain the rights to all international development, including clinical development, regulatory activities in the EU, and the supply of Ledaga® for commercial use.

Ledaga® (chlormethine hydrochloride) is a novel gel formulation, applied once a day, indicated for the topical treatment of mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL), a rare disease characterized by the abnormal accumulation of malignant T-cells in the skin. MF-CTCL is the most common type of cutaneous lymphoma and first presents as patches and plaques on the skin. It is difficult to diagnose, particularly in the early stages as many of its features are non-specific. Chlormethine is an alkylating agent that inhibits quickly proliferating cells and Ledaga® is recognized to have a good efficacy profile with a confirmed treatment response achieved in 76.7% of the efficacy evaluable population in the pivotal trial (Lessin S.R. et al JAMA Dermatol. 2013; 149(1): 25-32).

**Riccardo Braglia, Helsinn Group Vice Chairman and CEO, said:** “Mycosis fungoides-type cutaneous T-cell lymphoma is a disease which has a significant impact on quality of life. Helsinn is committed to solutions to treat and improve the symptoms of cancer, and we are pleased to initiate this collaboration with Orphan Europe, a trusted and highly reputable partner, to further the reach of Ledaga® to patients in need.”

**Andrea Recordati, Recordati group CEO, said:** “We are very pleased with the addition of this innovative treatment for MF-CTCL to our rare disease portfolio. The treatment of this rare disease still represents an unmet medical need as existing treatments have either limited efficacy or are non-approved, non-reimbursed cumbersome pharmacy compounded

formulations. Ledaga® has the potential to become a very important product and to significantly strengthen our rare disease portfolio globally. Launches are expected to start in the short term in the EU and, following, in the rest of our territories.”

### **About Ledaga®**

Ledaga® gel is an alkylating drug indicated for the topical treatment of MF-CTCL in adult patients. Ledaga® is a gel which is applied topically once a day. The drug has been approved by the European Commission (for MF-CTCL patients in all stages) and received Orphan Drug Designation. It will be commercially available upon completion of Post Authorisation Measures. In France it is provided through an “Autorisation Temporaire d’Utilisation (ATU) de cohort” since 2014.

For additional information please see the [EU Summary of Product Characteristics](#).

### **About the Helsinn Group**

Helsinn is a privately owned pharmaceutical group with an extensive portfolio of marketed cancer care products and a robust drug development pipeline. Since 1976, Helsinn has been improving the everyday lives of patients, guided by core family values of respect, integrity and quality. The Group works across pharmaceuticals, biotechnology, medical devices and nutritional supplements and has expertise in research, development, manufacture and the commercialization of therapeutic and supportive care products for cancer, pain and inflammation and gastroenterology. In 2016, Helsinn created the Helsinn Investment Fund to support early-stage investment opportunities in areas of unmet patient need. The company is headquartered in Lugano, Switzerland, with operating subsidiaries in Switzerland, Ireland, the U.S., Monaco and China, as well as a product presence in approximately 190 countries globally.

To learn more about Helsinn Group please visit [www.helsinn.com](http://www.helsinn.com)

### **About the Recordati group**

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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