



# NEWS RELEASE

## **RECORDATI: POSITIVE CONCLUSION TO THE DECENTRALIZED PROCEDURE FOR THE APPROVAL IN EUROPE OF PITAVASTATIN (LIVAZO®) FOR THE TREATMENT OF HYPERCHOLESTEROLAEMIA**

Milan, 15 July 2010 – Recordati announces the positive outcome of the Decentralized Procedure for the approval of pitavastatin (Livazo®, Alipza® and other brands) in Europe following the communication from the Reference Member State (MHRA, Medicines and Healthcare products Regulatory Agency, UK) and the agreement of all the Concerned Member States which was received by Kowa. Pitavastatin, 1mg, 2mg and 4mg tablets, is indicated for the reduction of elevated total cholesterol (TC) and LDL-C, in adult patients with primary hypercholesterolaemia and combined (mixed) dyslipidaemia when response to diet and other non-pharmacological measures is inadequate.

Pitavastatin is a statin licensed by Recordati from the European subsidiary of Kowa Company Limited, the Japanese pharmaceutical company, in the majority of the European market. It has been available on the market in Japan since 2003 and was recently launched in the U.S. by Kowa Pharmaceuticals America and its US co-promotion partner Eli Lilly. This medicinal product promises to be an effective new treatment for dyslipidemia, a condition characterized by altered levels of blood cholesterol and other lipids and associated with an increased risk for heart disease and stroke.

In controlled clinical trials, run by Kowa Pharmaceutical in Europe, involving more than 1,600 patients it was shown that pitavastatin induces a reduction in LDL-cholesterol (the “bad” cholesterol that contributes to formation of atherosclerotic plaques) and an increase in HDL-cholesterol (the “good” cholesterol that is removed from the arterial walls), a dual effect that should be regarded as highly relevant, since it appears to reduce the relative risk for cardiovascular complications. It has been shown that pitavastatin is minimally metabolized by the enzymes of the Cytochrome P-450 family, enzymes that play a key role in the metabolism of many drugs, thus minimizing the potential risk for unpredictable responses to treatment or for interaction with drugs metabolized by this pathway. Pitavastatin has an excellent safety profile and represents a new effective and safe treatment for dyslipidemia.

“The favourable conclusion of the regulatory process in Europe for the approval of pitavastatin confirms the validity of this new treatment for hypercholesterolaemia” declared Giovanni Recordati, Chairman and CEO. “The product, under the brand Livazo® and Alipza® represents a new and interesting therapeutic option for a condition which constitutes one of the risk factors for cardiovascular disease”.

*Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECI.MI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of over 2,800, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. It has headquarters in Milan, Italy, operations in the main European countries, and a growing presence in the new markets of Central and Eastern Europe. A European field force of around 1,400 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’s current and growing coverage of the European pharmaceutical market makes it a partner of choice for new product licenses from companies which do not have European marketing organizations. Recordati is committed to the research and development of new drug entities within the cardiovascular and urogenital*

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therapeutic areas and of treatments for rare diseases. Consolidated revenue for 2009 was € 747.5 million, operating income was € 162.2 million and net income was € 110.6 million.

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