



# NEWS RELEASE

## **RECORDATI: CARBAGLU<sup>®</sup> APPROVED BY THE FDA FOR USE IN THE U.S.A.**

*Milan, 19 March 2010* – Recordati announces the approval by the Food and Drug Administration (FDA) in the U.S. of the NDA submitted by Orphan Europe for the use of Carbaglu<sup>®</sup> (carglumic acid) in pediatric and adult patients for the treatment of acute hyperammonaemia due to the deficiency of the hepatic enzyme N-acetylglutamate synthase (NAGS deficiency) and as maintenance therapy for chronic hyperammonaemia due to NAGS deficiency.

NAGS deficiency, a very rare disease involving extremely high plasma levels of ammonia, which leads to permanent and irreversible damage of the central nervous system, is a lifelong serious life-threatening clinical condition. The symptoms start shortly after birth, rapidly leading to cerebral oedema, coma and eventually death without appropriate treatment. Rapid diagnosis and prompt effective treatment are essential to prevent patients from permanent neurological damage.

Carbaglu<sup>®</sup> is the only specific treatment of hyperammonaemia due to NAGS deficiency. Other available treatments are unspecific for this indication. When treatment with Carbaglu<sup>®</sup> is started early, patients have normal growth and neurological development, and most of them do not need protein dietary restrictions. Carbaglu<sup>®</sup> does not only save patients' lives, but also assures a good quality of life for patients on a continuous treatment.

“We are very pleased with the FDA’s timely decision to approve Carbaglu<sup>®</sup> and thus make this drug available for patients in the U.S. suffering from such a serious condition” stated Giovanni Recordati, Chairman and CEO. “This also represents a significant step in the development of our business dedicated to the treatment of rare and orphan diseases.”

*Recordati, established in 1926, is a European pharmaceutical group, listed on the Italian Stock Exchange (Reuters RECLMI, Bloomberg REC IM, ISIN IT 0003828271), with a total staff of over 2,950, 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 over 1,450 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 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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