

## **RECORDATI RECEIVES ORPHAN DRUG DESIGNATION FOR ITS INVESTIGATIONAL TREATMENT FOR MSUD**

*Milan, 5 November 2018* –Recordati today announced that the European Commission (EC) has granted Orphan Drug Designation to Orphan Europe's (a Recordati group company) investigational product REC 0545 for the treatment of maple syrup urine disease (MSUD). This is the first time that an Orphan Drug Designation has been granted in this indication.

MSUD is a rare genetic metabolic disorder in which the body is unable to properly process certain amino acids (the building blocks of proteins). Beginning in early infancy, this condition is characterized by lack of appetite, vomiting, lack of energy (lethargy), seizures, abnormal movements and developmental delay. The condition gets its name from the distinctive sweet odour of affected infants' urine. Patients with Maple syrup disease suffer from decompensation episodes that can be life-threatening if untreated. In Europe around 3000 patients are affected by MSUD.

Orphan drug designation applies to drugs that seek to treat rare diseases or conditions affecting fewer than 5 in 10 000 inhabitants in the EU while providing significant therapeutic advantage over existing therapies. The designation provides the opportunity for ten years marketing exclusivity upon approval of the product in the designated indication.

“The European orphan drug designation is a key regulatory achievement that will further facilitate and accelerate our development of REC 0545 for the treatment of MSUD. We are very pleased that the EC granted orphan drug designation to our new treatment, which highlights the unmet medical need for children and adults with this devastating disease and confirms the need for development of novel therapies for MSUD” stated Andrea Recordati, CEO. “This also represents another important milestone for our company and demonstrates our commitment to the area of rare diseases.”

*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.*

For further information:

Recordati website: [www.recordati.com](http://www.recordati.com)

### Investor Relations

Marianne Tatschke  
(39)0248787393  
e-mail: [investorelations@recordati.it](mailto:investorelations@recordati.it)

### Media Relations

Studio Noris Morano  
(39)0276004736, (39)0276004745  
e-mail: [norismorano@studionorismorano.com](mailto:norismorano@studionorismorano.com)

*Statements contained in this release, other than historical facts, are "forward-looking statements" (as such term is defined in the Private Securities Litigation Reform Act of 1995). These statements are based on currently available information, on current*  
**RECORDATI INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.**

Sede Legale  
VIA M. CIVITALI, 1  
20148 MILANO, ITALIA  
TEL. (39) 0248787.1  
FAX (39) 0240073747

CAPITALE SOCIALE € 26.140.644,50 I.V.  
REG. IMP. MILANO N. 00748210150  
CODICE FISCALE/P.IVA 007482210150  
R.E.A. MILANO N. 401832

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