

## **RECORDATI ANNOUNCES MARKETING APPROVAL FOR CYSTADROPS®**

*Milan, 27 January 2017* - Recordati announces that the European Union Commission has granted the European marketing authorization for its orphan medicinal product Cystadrops® 3.8mg/mL. Cystadrops® is the first eye-drop solution containing cysteamine hydrochloride approved in the European Union for "the treatment of corneal cystine crystal deposits in adults and children from 2 years of age with cystinosis". The European Commission granted Cystadrops® orphan drug designation in November 2008.

Cystinosis is a rare congenital lysosomal storage disorder recognized as a severe life threatening condition. Cystinosis is characterized by an accumulation of cystine crystals which negatively affects all organs in the body, especially the kidneys and eyes. The cystine crystal deposits start in the cornea, leading progressively to increased sensitivity to light (photophobia), corneal surface deterioration (keratopathy) and loss of vision. Cystinosis benefits from systemic treatment with cysteamine orally administered. However, oral cysteamine does not adequately address ocular cystinosis because of the non-vascularization of cornea. Without a proper, continued, local eye treatment, cystine crystals accumulate in the cornea, leading to severe ophthalmic consequences and possibly to blindness in the long term.

Cystadrops® eye-drop solution has been developed specifically for cystinosis patients by Orphan Europe (Recordati Group). Cystadrops® is available as a 3.8 mg/mL eye-drop solution. The active substance of Cystadrops® is cysteamine, a cystine-depleting agent. The benefit of Cystadrops® is its ability to reduce corneal cystine crystal accumulation.

Cystadrops® is the first pharmaceutical product to be approved in the European Union for this indication.

The formulation of Cystadrops® allows four instillations per day which should considerably favour patient's compliance with the treatment and decrease ophthalmic complications for all patients suffering from cystinosis.

"We are extremely pleased that the European Commission has granted the marketing approval for Cystadrops®, an important therapeutic solution for the ophthalmic complications affecting cystinosis patients" declared Andrea Recordati, Vice Chairman and Chief Executive Officer. "The product had already been made available to patients through early access programs in Europe and in some other countries and therefore many patients affected by the ocular manifestations of cystinosis have already been able to benefit from treatment with Cystadrops®."

*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 around 4,000, dedicated to the research, development, manufacturing and marketing of pharmaceuticals. Headquartered in Milan, Italy, Recordati has operations in the main European countries, in Russia, in other Central and Eastern European countries, in Turkey, in North Africa, in the United States of America and in some Latin American countries. 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 within the urogenital therapeutic area and of treatments for rare diseases. Consolidated revenue for 2015 was € 1,047.7 million, operating income was € 278.5 million and net income was € 198.8 million.*

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